



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61B 17/08	A1	(11) International Publication Number: WO 99/21490
		(43) International Publication Date: 6 May 1999 (06.05.99)

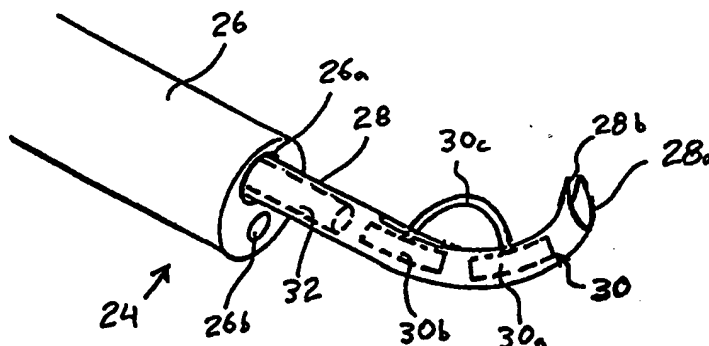
(21) International Application Number: **PCT/US98/13342**(22) International Filing Date: **25 June 1998 (25.06.98)**(71) Applicant (for all designated States except US): **TRANSVASCULAR, INC. [US/US]; 1505-D Adams Drive, Menlo Park, CA 94025 (US).**

(72) Inventors; and

(75) Inventors/Applicants (for US only): **MAKOWER, Joshua [US/US]; 450 Tyndall Street, Los Altos, CA 94022 (US). FLAHERTY, Christopher, J. [US/US]; 11 Pine Lane, Los Altos, CA 94022 (US). MACHOLD, Timothy, R. [US/US]; 65 Bernal Avenue, Moss Beach, CA 94022 (US). GARBOTTO, John, Thomas [US/US]; 6284 Lido Court, Newark, CA 94022 (US). WHITT, Jason, Brian [US/US]; 2554 Franklin Street, San Francisco, CA 94133 (US).**(74) Agent: **BUYAN, Robert, D.; Stout, Uxa, Buyan & Mullins, LLP, Suite 210, 100 Pacifica, Irvine, CA 92618 (US).**(81) Designated States: **AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).****Published***With international search report.**Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.**Upon the request of the applicant, before the expiration of the time limit referred to in Article 21(2)(a).**With an indication in relation to a priority claim considered not to have been made.*(54) Title: **TRANSLUMINAL METHODS AND APPARATUS FOR CLOSING, FORMING ATTACHMENTS TO, AND/OR FORMING ANASTOMOTIC JUNCTIONS IN, LUMINAL ANATOMICAL STRUCTURES**

(57) Abstract

A method and apparatus for passing attachment apparatus (20), (e.g., connector devices, staples, etc.) or connector material (88), (e.g., suture thread, wire, cord, filament, monofilament, etc.) into or through the wall of a luminal anatomical structure (e.g., a blood vessel or other anatomical conduit), for the purpose of closing the lumen of the anatomical structure, forming an anastomotic junction between separate anatomical structures (or between approximated segments of the same anatomical structure), and/or attaching an article (e.g., an endoluminal, extraluminal or transluminal graft) or other apparatus to the wall of the anatomical structure.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

5 **TRANSLUMINAL METHODS AND DEVICES FOR CLOSING, FORMING
ATTACHMENTS TO, AND/OR FORMING ANASTOMOTIC JUNCTIONS IN,
LUMINAL ANATOMICAL STRUCTURES**

Field of the Invention

10 The present invention relates generally to medical devices and methods, and more
particularly to intraluminal devices and methods for passing attachment apparatus (e.g.,
connector devices, staples, etc.) or connector material (e.g., suture thread, wire, cord, filament,
monofilament, etc.) into or through the wall of a luminal anatomical structure (e.g., a blood
vessel or other anatomical conduit) for the purpose of ; i) closing the lumen of the anatomical
15 structure, ii) forming an anastomotic junction between separate anatomical structures (or between
approximated segments of the same anatomical structure), and/or iii) attaching an article (e.g.,
an endoluminal, extraluminal or transluminal graft) or other apparatus to the wall of the
anatomical structure.

Background of the Invention

20 In modern medical practice, it is sometimes desirable to pass attachment apparatus (e.g.,
connector devices, staples, etc.) or connector material (e.g., suture thread, wire, cord, filament,
monofilament, etc.) into or through the wall of a luminal anatomical structure (e.g., a blood
vessel or other anatomical conduit) for the purpose of ; i) closing the lumen of the anatomical
structure, ii) forming an anastomotic junction between separate anatomical structures (or between
approximated segments of the same anatomical structure), and/or iii) attaching an article (e.g.,
25 an endoluminal, extraluminal or transluminal graft) or other apparatus to the wall of the
anatomical structure. Some of these types of medical procedures are summarized as follows:

**i. Procedures for Fully or Partially Closing of the Lumen
of a Tubular Anatomical Structure Such As a Blood Vessel**

30 Examples of medical procedures wherein it is desirable to close the lumen of a blood
vessel include: a) procedures intended to diminish or block the flow of blood into vascular
aneurysms (e.g., cerebral aneurysms); b) procedures intended to occlude the side branches which
emanate from a segment of a peripheral vein (e.g., to prepare the vein segment for use as an in
situ bypass conduit); c) procedures intended to occlude varicose veins; d) transvascular,

catheter-based procedures for bypassing obstructed, diseased or injured arteries as described in United States Patent Application Serial Nos. 08/730,327 and 08/730,496; e) procedures intended to block or diminish blood flow to a tumor; f) procedures intended to close congenital or acquired arteriovenous malformations; g) procedures intended to temporarily or permanently block blood flow through a vessel as an adjuvant to placement of an implant or apparatus within the blood vessel (e.g., placement of an endovascular graft for treatment of an aneurysm or other therapeutic intervention); and procedures intended to close an interstitial puncture tract or fistula which has been created for use in performing another medical procedure. Included among the catheter-based arterial bypass procedures described in co-pending Application Nos. 08/730,327 and 08/730,496 is a coronary artery bypass procedure wherein a passageway-forming catheter is transluminally advanced into the coronary vasculature, and a tissue-penetrating element is passed out of the catheter and through the wall of the vessel in which the catheter is positioned to create at least one blood flow passageway (e.g., a puncture tract or interstitial tunnel) between an obstructed coronary artery and an adjacent coronary vein. Arterial blood then flows from the obstructed coronary artery into the adjacent coronary vein. In one variation of the procedure, a single arteriovenous passageway is formed (i.e., a "first" blood flow passageway) and the lumen of the coronary vein is blocked or closed off immediately proximal to such first blood flow passageway, such that arterial blood will enter the vein and will be forced to flow through the vein, in the retrograde direction. In this manner, the arterial blood from the obstructed artery may retroperfuse the myocardium through the coronary vein. In another variation of the procedure, one or more secondary arteriovenous passageways (e.g., puncture tracts or interstitial tunnels) may be formed between the coronary vein into which the arterial blood has been shunted, and the obstructed artery or another coronary artery. These secondary passageway(s) allow the rerouted arterial blood to re-enter the coronary arterial tree after having bypassed the arterial obstruction. In cases wherein such secondary blood flow passageways are formed, the lumen of the coronary vein may additionally be blocked or closed off at location(s) distal to such secondary passageway(s), to cause the rerouted arterial blood to re-enter the arterial vasculature, as desired.

ii. Procedures Which Require the Formation of an Anastomotic Connection to the Wall of A Luminal Anatomical Structure

Various types of anastomotic connections are frequently formed in luminal

anatomical structures for the purpose of connecting opposing transected ends or openings formed in anatomical conduit(s) (e.g., blood vessel, intestine, etc.) or for connecting an opening formed in an anatomical conduit to another anatomical structure. When joining the juxtaposed ends or openings of a singular anatomical conduit which has been transected, or when joining the juxtaposed ends or openings of two (2) different anatomical conduits, such joiner(s) may be accomplished by either 1) end-to-end, 2) end-to-side, or 3) side to side anastomosis. Irrespective of which type of anastomotic connection is being formed, the usual surgical technique requires that the luminal anatomical conduit(s) be maneuvered into proximity and placed in abutting juxtaposition, such that the ends or openings of the anatomical conduit(s) are in alignment with one another. Thereafter, sutures, staples or other connecting apparatuses are passed through the walls of the juxtapositioned anatomical conduit(s) to form the desired anastomotic connection therebetween. Anastomotic connections of this type are frequently performed during surgical procedures wherein a diseased or injured segment of an anatomical conduit (e.g., blood vessel, intestine, etc.) has been resected and removed, and the opposing cut ends of the conduit are then reconnected (by end-to-end, side to side, or end to side anastomosis) to permit continued flow of bodily fluids or other matter through the conduit.

iii. Procedures Wherein Grafts or Other Articles are Attached to A Luminal Anatomical Structure

Examples of medical procedures wherein it is desirable to anchor or attach a graft or other apparatus to the wall of a blood vessel or other luminal anatomical conduit include certain endovascular grafting procedures wherein a tubular graft is placed within the lumen of an aneurysmic blood vessel to create a neo-lumen or artificial flow conduit through the aneurysm, thereby eliminating the exertion of blood pressure on the aneurysm and allowing the aneurysmic space to subsequently become filled in with granulation tissue. These endovascular grafting procedures have heretofore been used to treat aneurysms of the abdominal aorta, as well as aneurysms of the descending thoracic aorta. The endovascular grafts which have heretofore been used for these procedures typically incorporate or are combined with one or more radially expandable stents which are radially expanded in situ to anchor the tubular graft to the wall of the blood vessel at sites upstream and downstream of the aneurysm. However, in the event that these stent(s) fail to establish sound frictional engagement with the blood vessel wall, the graft

may undergo undesirable migration or slippage, or blood may leak into the aneurysmic sac (sometimes referred to as an "endoleak").

Thus, in view of the above-mentioned undesirable complications associated with the use of radially expandable stents to frictionally anchor a graft or other apparatus to the wall of a blood vessel (or other luminal anatomical structure) there exists a need in the art for the development of new endoluminal suturing devices which may be used to suture the opposite ends of a endoluminal tube graft (or other article) to the surrounding wall of a blood vessel or other tubular anatomical conduit, thereby ensuring sound and permanent placement of the graft or other article. Also, in view of the other types of medical procedures described hereabove, there also exists a need in the art for the development of new transluminal methods and apparatus for closing the lumen of a luminal structure and/or for forming an anastomotic connections within or to the wall of the luminal structure.

Summary of the Invention

The present invention provides intraluminal devices and methods which are useable to i) fully or partially close the lumen of a luminal anatomical structure (e.g., a blood vessel), ii) form anastomotic junctions between or connections to luminal anatomical structure(s) and/or iii) attach an endoluminal, extraluminal or transluminal graft or other apparatus to the wall of a luminal anatomical structure.

i. First Embodiment-Clock Spring Occluder

In accordance with a first embodiment of the invention, there is provided an intraluminal device which is useable to occlude luminal anatomical structure by way of a closure device referred to herein, for purposes of convenience only, as a "clock spring" occluder. This device comprises an elongate catheter which is insertable into a luminal structure, and a resilient coil which is advancable out of the catheter and at least partially through the wall of the luminal anatomical structure to occlude the lumen of the anatomical structure. This resilient coil may optionally have one or more engagement members (e.g., barbs or hooks) formed thereon to enhance its engagement or gripping of the anatomical structure and to prevent the coil from slipping or pulling back through the puncture tract through which it is advanced into or through the anatomical structure wall. Generally, a first end of the resilient coil is advancable out of the catheter and at least partially through the wall of the luminal structure (e.g., blood vessel) within

which the catheter is positioned. Thereafter, the coil is further advanced within or outside of the wall of the anatomical structure so as to fully or partially encircle or surround the lumen of the anatomical structure (e.g., it may slidably advance around the adventitial surface of a blood vessel). The optional engagement members (hooks or barbs), if present, will protrude into, grip, 5 adhere to or otherwise engage the wall of the luminal anatomical structure in a manner which will prevent the coil from slipping or pulling back through the puncture tract which it has formed into or through the anatomical structure wall and/or to prevent the from uncoiling in any way which would cause the lumen of the anatomical structure to return to its open configuration.

After the coil has been fully advanced out of the catheter, the catheter may be extracted 10 and removed, leaving the coil in place. The coil is biased to a coiled or closed configuration such that it will then draw the wall of the luminal structure inwardly so as to fully or partially close the lumen of the anatomical structure.

ii. Second Embodiment T-Occluder/Connector Apparatus

In accordance with a second embodiment of the invention, there is provided another 15 intraluminal device, which is useable to occlude or to form anastomoses in/attachments to a luminal anatomical structure. This second embodiment comprises a catheter and an occluder/connector apparatus which is advancable out of the catheter and at least partially through the wall of the luminal anatomical structure to occlude or for attachments to/anastomoses in that anatomical structure. For purposes of convenience only this occluder/connector apparatus 20 will be referred to herebelow as a T-occluder/connector device. In general, this embodiment comprises an elongate catheter having a hollow puncturing member (e.g. a needle) which is advancable out of the catheter and through the wall of the anatomical structure. One or more of the T-occluder/connector device(s) is/are loaded into the lumen of the puncturing member. Each such T-occluder/connector device generally comprises an elongate link (e.g., a thread, wire, 25 strand, cord, etc.) having first and second engagement members (e.g., crossbars, flanges, hooks, barbs, adhesive, clips, etc.) formed on either end thereof. After the catheter has been advanced to the desired site within the luminal structure, the puncturing member is advanced out of the catheter and at least partially through the wall of the luminal structure, at a first location. Thereafter a first one of the engagement members of a T-occluder/connector device is advanced 30 out of the puncturing member to engage the wall of the luminal anatomical structure at a first location. Then, the puncturing member is retracted into the lumen of the anatomical structure

and is moved or reoriented therewithin. Thereafter, the puncturing member is advanced (a second time) at least partially through the wall of the luminal anatomical structure, at a second location thereon. Thereafter, the second engagement member of that T-occluder/connector device is expelled from the puncturing member to engage the wall of the anatomical structure at the second location. This procedure may be repeated to install the desired number of T-occluder/connector devices at the desired locations about the wall of the luminal anatomical structure. When the procedure is completed, the puncturing element and catheter are removed, leaving the previously installed T-occluder/connector device(s) in place. Depending on the particular application, the link portion(s) of the T-occluder/connector device(s) may be formed of rigid, pliable, elastic, nonelastic, malleable, nonmalleable, retractable or nonretractable material to exert the desired amount of inward pulling force upon the engagement members. This inward pulling of the engagement members results in the desired occlusion of the lumen of the anatomical structure or the desired anastomosis in or attachment to its wall.

iii. Third Embodiment-Twist Clip Occluder

In accordance with a third embodiment of the present invention, there is provided another intraluminal device which is useable to occlude the lumen of an anatomical structure (e.g., a blood vessel) by way of a closure device referred to herebelow for purposes of convenience only as a "Twist Clip Occluder". This device generally comprises an elongate catheter having an elongate twistable clip member formed of bendable (i.e., malleable) material loaded in the catheter and advance able from the catheter and at least partially through the wall of the luminal anatomical structure. After the clip member has been advanced into or around the wall of the anatomical structure, the catheter (or a secondary twisting tool) is rotated so as to twist the clip member to a closed configuration wherein it will draw the wall of the luminal anatomical structure inwardly so as to fully or partially close its lumen.

iv. Fourth Embodiment Transluminal Suturing Device

In accordance with a fourth embodiment of the present invention, there are provided catheter-based devices for installing sutures, staples or other connector apparatus into the wall of one or more luminal anatomical structure(s) (e.g., blood vessel(s), intestine(s), duct(s), or other anatomical conduit(s)). For purposes of convenience only, these devices of the present invention will be referred to herein as "intraluminal suturing devices", although it will be appreciated that various types of connector materials (e.g., wire, staples, absorbable sutures,

nonabsorbable sutures, etc.) may be installed by use of these devices.

a. inboard needle type

One type of intraluminal suturing device of the present invention comprises an elongate rigid or pliable catheter which is advance able into the lumen of a luminal anatomical structure, and which has i.) a tissue inlet opening into which a portion of the wall of the luminal structure may be caused to intrude (i.e., lapse, invaginate, extend inwardly, etc.) and ii.) an axially reciprocating penetrating member (e.g., a needle) having a suture thread, staple, wire or other connector material attached thereto. The penetrating member is mounted within the catheter, adjacent the tissue inlet opening and generally parallel to the longitudinal axis of the catheter, such that the penetrating member may be alternately passed back and forth through the portion(s) of the luminal structure wall which protrude into the tissue inlet opening. In operation, this inboard needle type device may be used by advancing the catheter into the lumen of the anatomical structure and causing a portion of the wall of the anatomical structure to intrude into the tissue inlet opening of the catheter such that some of the tissue is positioned in the path of the axially reciprocating penetrating member. The penetrating member, with its attached suture thread, staple or other connector material, is then passed through the intruding mass of tissue a first time. If it is desired to pass the suture material or other connector material through the wall of the anatomical structure more than once (e.g., to form an uninterrupted suture line) the catheter may then repositioned within the luminal anatomical structure (e.g., rotated and/or longitudinally advanced and/or longitudinally retracted) and another portion of the wall of the anatomical structure will caused to intrude into the tissue inlet opening such that some of that tissue is located in the path of the axially reciprocating penetrating member. The penetrating member, with its attached suture thread, staple or other connector material, is then once again passed through the intruding mass of tissue. These operational steps are repeated as many times as necessary to form the desired anastomosis or connection.

In some applications, the suture material or other connector material will be drawn taught and knotted in the nature of a "purse string" so as to draw the wall of the anatomical structure inwardly and to fully or partially close its lumen. These operational steps may be repeated numerous times, as necessary, to form the desired anastomosis in, or connection to, the wall(s) of the luminal anatomical structure(s). In other applications, the suture material or other connector material will be knotted or tied (one or more times) without having been drawn

taught, so as to allow the lumen to remain open, while forming the desired anastomotic connection in, or attachment to, the wall of the luminal structure.

b. outboard needle type

5 An alternative type of intraluminal suturing device of the present invention generally comprises an elongate rigid or pliable catheter which is advance able into the lumen of a luminal anatomical structure, such catheter having i.) a first penetrating member lumen from which a penetrating member may pass out of a first opening in the side of the catheter, ii.) a second penetrating member lumen into which the penetrating member may pass through a second opening formed in the side of the catheter, and iii.) a preshaped, pliable penetrating member 10 which is passable a) from the first lumen, b) out of the first opening, c) through an adjacent portion of the wall of the luminal anatomical structure, d) into the second opening and d) into the second lumen. A suture thread, or other connector material as described hereabove, is attached to the penetrating member such that it is drawn by the penetrating member through the tissue.

In operation, this outboard needle type of intraluminal suturing device may be used by 15 advancing the catheter into the lumen of an anatomical structure such that the first and second openings of the catheter are located adjacent a first portion of the wall of the anatomical structure. The penetrating member (and the suture thread or other connector material attached thereto) is then passed from first lumen, out of the first opening, through the first portion of tissue, into the second opening and into the second lumen. In applications where it is desired to 20 pass the suture thread or other connector material repeatedly through the wall of the anatomical structure (e.g., an uninterrupted suture line) the catheter will then be repositioned (e.g., rotated and/or longitudinally advanced and/or longitudinally retracted) such that a second portion of tissue is adjacent the first and second openings of the catheter, and the foregoing procedural steps are then repeated.

25 **v. Fifth Embodiment- Device Useable to Form Attachments or Anastomoses**

Further in accordance with the invention, there is provided a device for forming attachments to, or anastomoses in, a luminal anatomical structure. This device generally comprises an elongate catheter wich is insertable into the lumen of the luminal anatomical structure and a hollow needle disposed within said catheter, said needle having a sharpened distal 30 tip, a needle lumen which extends longitudinally therethrough, and an outlet opening formed in communication with said needle lumen. The needle is avancable out of the catheter, after the

catheter has been inserted into the luminal anatomical structure, such that the sharpened distal tip of the needle will puncture through the wall of the anatomical structure and the outlet opening of the needle will become situated outside of the luminal anatomical structure. At least one attachment apparatus is initially loaded into the lumen of the needle. Each attachment apparatus generally comprises a flexible link (e.g., a cord, thread, strand, or elongate member) having first and second engagement members (e.g., t-bars, flanges, arms, etc.) formed on opposite ends thereof. These engagement members are able to advance, one at a time, out of the outlet opening of the needle. While loaded in the lumen of the needle, the engagement members may be connected to one another, in a chain-like fashion, so that they may be advanced and/or retracted as a unit. After the catheter has been inserted into the luminal anatomical structure, the needle is advanced (a first time) out of the catheter and through a first location on the wall of the luminal anatomical structure. Thereafter, one engagement member is passed out of the outlet opening of the needle so that it becomes deployed outside of or within the wall of the luminal anatomical structure so as to engage the wall. The needle is then retracted into the catheter and the catheter is repositioned (e.g., rotated and/or longitudinally advanced/retracted) within the lumen of the anatomical structure. The needle is then advanced (a second time) out of the catheter and through a second location on the wall of the luminal anatomical structure. The second engagement member is then advanced out of the outlet opening of the needle so that it becomes deployed outside or within the wall of the anatomical structure and will engage the wall, adjacent the second location. The needle is then retracted into the catheter, leaving the two (2) engagement members in abutting engagement with the first and second locations on the wall of the anatomical structure, with the link portion of the attachment member traversing therebetween. Depending on the number of attachment members required to form the desired attachment or anastomosis, this procedure may then be repeated one or more times. When the desired attachment or anastomosis has been completed, the catheter and accompanying needle are removed from the body, leaving the previously installed attachment members in place. The attachment members may be formed of absorbable or non-absorbable material, depending of the nature of the application.

This embodiment of the invention may be used to attach various items (e.g., endoluminal grafts, stents) to the wall of a luminal anatomical structure, or may be utilized to form an anastomotic junction between the approximated ends of one or more anatomical conduit(s) (e.g.,

the opposing cut ends of a blood vessel, fallopian tube, ureter, urethra, pancreatic duct, common bile duct, esophagus, intestine, or other conduit which has been cut or resected). Further objects and advantages of the present invention may become apparent to those skilled in the art upon reading and understanding of the following detailed description, and the accompanying drawings.

5

Brief Description of the Drawings

Figure 1 is a partial longitudinal sectional view of an adjacent artery and vein wherein a lumen closing device has been used to install a clock-spring occluder apparatus of the present invention to close the lumen of the vein.

10

Figure 1a is an elevational view of a preferred clock spring occluder apparatus of the present invention, which forms a component of the device shown in Figure 1.

Figures 2-5 are a step-by-step showing of a preferred method for using the device of Figure 1 to accomplish closure of a blood vessel.

Figure 6 is a cross sectional view through line 6-6 of Figure 5.

15

Figure 7 is a partial perspective view of intraluminal device of the present invention which incorporates a T-occluder apparatus for closing the lumen of a blood vessel.

Figures 8-11 are step-by-step showings of a method by which the device of Figure 7 is used to effect closure of the lumen of a blood vessel using a T-occluder apparatus having an elastic link.

20

Figures 12-17 are step-by-step showings of a method for using the device of Figure 7 to effect closure of the lumen of a blood vessel using a T-occluder apparatus having a twistable or knottable link.

Figure 18 is a perspective view of an intraluminal suturing device of the present invention having an inboard tissue-penetrating element which is useable to pass a connector material (e.g., suture thread) through the wall of a luminal anatomical structure.

25

Figure 18a is a longitudinal sectional view of a portion of the device of Figure 18.

Figure 19a-19b are step-by-step showings of a preferred method of using the device of Figures 18-18a to place a continuous "purse string" suture which is useable to ligate the lumen of the anatomical structure.

30

Figure 20 is a longitudinal sectional view of a segment of a blood vessel illustrating the manner in which the device of Figures 18-18a may be used to suture the ends of an endoluminal

tube graft within a blood vessel so as to bridge an aneurysm.

Figure 21 is an enlarged longitudinal sectional view of the distal portion of the device shown in Figures 18-18a, operatively positioned within a blood vessel.

5 Figure 21a is a perspective view of the C-shaped distal segment of the preferred needle advancing/retracting component of the device of Figures 18-18a & 21.

Figure 21b is a cross sectional view through line 21b-21b of Figure 21.

Figure 21c is a cross sectional view through line 21c-21c of Figure 21.

Figure 21d is a cross sectional view through line 21d-21d of Figure 21.

10 Figure 22 is a perspective view of another intraluminal suturing device of the present invention, having an inboard tissue penetrating member which is moved by way of a modified advancing/retracting component.

Figures 23a-23h are partial longitudinal sectional views showing, in step-by-step fashion, a preferred method of using an intraluminal suturing device of the present invention having an outboard tissue penetrating member.

15 Figure 24a is a cross-sectional view through line 24a-24a of Figure 23a.

Figure 24b is a cross-sectional view through line 24b-24b of Figure 23a.

Figure 25 is a perspective view of the needle advancing/retracting member of the device shown in Figures 23-24.

Figure 25a is a distal end view of the needle advancing/retracting member of Figure 25.

20 Figure 26 is an enlarged, partial, side elevational view of the tissue penetrating member of the device of Figures 23-24.

Figure 27 is a partial perspective view of a device of the present invention for forming attachments to and or anastomoses in, the wall of a luminal anatomical structure using modified T-connector apparatus.

25 Figure 27a is a cut-away perspective view of a segment of a blood vessel, showing the manner in which the device of Figure 27 may be used to anchor an endoluminal graft within a blood vessel.

Figure 27b is an end perspective view of the showing of Figure 27a.

30 Figure 27c is a cut-away perspective view of a tubular anatomical structure which has been transected and subsequently reconnected, by end-to-end anastomosis, using the device of Figure 27.

Figure 27d is a perspective view of two (2) tubular anatomical conduits which have been prepared and approximated in end-to-side fashion, and which have been anastomosed by way of interrupted connector bars which are a variation of the device shown in Figure 27.

5 Figure 28a is a longitudinal sectional view of two (2) anatomical conduits being connected by end-to-side anastomosis using an intraluminal device of the present invention.

Figure 28b is a longitudinal sectional view of the two (2) anatomical conduits of Figure 28a, after undergoing end-to-side anastomosis by an intraluminal device of the present invention.

Figure 29a is a longitudinal sectional view of two (2) anatomical conduits being connected by side-to-side anastomosis using an intraluminal device of the present invention.

10 Figure 29b is a longitudinal sectional view of the two (2) anatomical conduits of Figure 29a, after undergoing side-to-side anastomosis by an intraluminal device of the present invention.

Detailed Description of the Preferred Embodiments

15 The detailed description set forth below in connection with the appended drawings is intended merely as a description of the presently preferred embodiments of the invention, and is not intended to represent the only forms in which the present invention may be constructed or utilized. This description makes reference to the structural and functional elements of a number of presently preferred or exemplary embodiments of the invention. It is to be understood, however, that the same or equivalent structure and/or function may be accomplished by
20 numerous other embodiments of the invention which are not specifically described herebelow, but which are intended to be encompassed within the spirit and scope of the invention.

i. First Embodiment-Clock Spring Occluder

A clock spring occluder 20, more clearly seen in Figure 2a, comprises a generally spiral-shaped coil having a first outwardly oriented end 20a and a second inwardly oriented end 20b. The clock
25 spring occluder may further have a multiplicity of outwardly extending engagement members, such as protrusions or barbs 20c which, as will be discussed below, enhance the ability of the occluder 20 to securely grasp and occlude the lumen of an anatomical structure such as a blood vessel.

30 The clock spring occluder 20 is deployed through the lumen of the catheter 18, as shown schematically in Figure 1. The catheter 18 is inserted and positioned within the vessel 16 such that side opening 18a formed at the distal end of the catheter 18 is aligned with and

juxtapositioned with a portion of the vessel wall 16, at the location where it is desired to occlude the vessel. The first outwardly oriented end 20a of the clock spring occluder 20 is then advanced through the side opening 18a of the catheter 18 and through at least a portion of the vessel wall 16. To facilitate such puncture through vessel wall 16, the outward end 20a of the device 20 may optionally be sharpened. The clock spring occluder 20 is then advanced through the puncture site so that it fully or partially surrounds the lumen 22 of the vessel and engages the vessel wall.

The occluder device 20 is biased to a coiled configuration which causes it to pull the wall of the vessel inwardly so as to collapse and close the lumen of the vessel at the desired location, as shown in Figure 4.

To enhance the ability of the clock spring occluder 20 to engage and pull the vessel wall, one or more engagement members, such as outwardly projecting barbs 20c may be formed on the occluder device 20 to prevent the device 20 from migrating, slipping or pulling through the wall 16 of the vessel. Once the entire length of the clock spring occluder 20 has been advanced through the side opening 18a, the catheter 18 is then removed, as illustrated in Figure 5. After the catheter 18 has been removed, the occluder 20 will resiliently retract to its preformed coiled configuration to cause the vessel to assume a closed "hourglass" shape, as further illustrated by Figure 6. The tightness of the coiled configuration of the occluder device 20 will determine whether the lumen of the vessel is fully or partially occluded, as desired.

ii. Second Embodiment- T Occluder Apparatus

Figures 7-11 and 23-23b show a second embodiment of a transluminal device 24 which is useable for ligating a luminal structure, such as a blood vessel, or for the other applications such as anchoring or attaching an endoluminal graft or other endoluminal apparatus to the wall of the luminal structure (e.g., blood vessel).

This second embodiment of the intraluminal device 24 comprises an elongate rigid or pliable catheter 26 having a first lumen 26a and a second lumen 26b extending longitudinally therethrough. A hollow needle 28, which has an elongate slot 28b formed in one side thereof adjacent its distal end 28a, is slidably disposed within the first lumen 26a of the catheter 26 so as to be advancable out of the catheter, as shown. The second lumen 26b may be used for passage of a guidewire, to permit the catheter 26 to be advanced over a pre-positioned guidewire.

Disposed within the hollow bore of the curved needle 28 is a T-occluder apparatus 30 or 30'. The T-occluder apparatus generally comprises an elongate link member such as a pliable

cord 30c and first 30a, 30a' and second 30b, 30b' engagement members attached to the other end thereof. In the particular design shown in the drawings, the engagement members 30a, 30a', 30b, 30b' are in the form of cross members, but it will be appreciated that these engagement members 30a, 30a', 30b, 30b' may be any suitable type of structure or material (e.g., projection, flange, hook, barb, adhesive, staple, etc.)capable of engaging and/or connecting ti the wall of the luminal anatomical structure to be occluded. In the particular embodiment shown, the cross-members 30a, 30a', 30b, 30b' are initially disposed in direct alignment within the hollow inner bore of the needle 28, such that the cross-members 30a, 30a', 30b, 30b' are in serial end-to-end alignment within the bore, and are substantially parallel to the longitudinal axis of the needle 28. In this manner, some or all of the cord 30c may protrude out of the elongate slot 28b formed in the side of the needle, in the manner shown in Figure 7.

A push rod 32 is slidably disposed within the bore of the needle 28, behind the T-occluder apparatus 30, 30' loaded therewithin. In this manner, the push rod 28 may be utilized to expel the first and second cross-members 30a,30a',30b, 30b' out of the distal end 28a of the needle 28.

In one design shown in Figures 7-11, the cord 30c may be formed of elastic material which is elastically biased to a shortened configuration such that the cord 30c will pull or draw the cross-members 30a, 30b inwardly toward a common central point or location. In another design shown in Figures 12-15 the cord 30c' may be formed of material which is capable of being wound (i.e., a malleable material which can be plastically deformed, twined or kinked--or a pliable material capable of being tied or knotted) such that the overall length of the cord 30c' becomes shortened, thereby drawing the cross members 30a', 30b' inwardly toward a common central point or location.

In normal operation, the catheter 26 is advanced to its desired location within a blood vessel or other luminal anatomical structure. The positioning of the catheter 26 may be guided or verified by any suitable imaging or guidance system and, optionally, a fiberoptic endoscope, ultrasound imaging system, or any other on-board imaging system may be incorporated into the catheter to provide an image of the area adjacent a view port 26b or other imaging location on the catheter 26.(see Figure 7) Once the catheter 26 has been placed in the desired position, the needle 28 is advanced out of the catheter 26 and the distal end 28a of the needle is passed fully or partially through the wall of the luminal anatomical structure, at a first location. The push rod

32 is then advanced through needle 28 in the distal direction such that the first engagement member 30a, 30a' of the first T-occluder 30, 30' is expelled out of the needle 28 so that it will engage the wall of the luminal anatomical structure, adjacent the first location. Thereafter, as shown in Figure 9, the needle 28 is retracted into the lumen of the anatomical structure 34 and the catheter is moved (e.g., rotated approximately 180 degrees). Thereafter, the needle 28 is once again advanced such that the distal end 28a of the needle 28 passes fully or partially through the wall of the luminal anatomical structure 34 at a second location which is diametrically opposite the first location. (see Figures 10 and 13) The push rod 32 is then once again advanced in the distal direction to expel the second engagement member 30b, 30b' out of the distal end 28a of the needle and into engagement with the wall of the anatomical structure 34 adjacent the second location.

When the design of Figures 7-11 is installed in the foregoing manner, the elastic cord 30c will resiliently shorten and will pull the engagement members 30a, 30b inwardly so as to collapse the wall of the anatomical structure 34 and fully or partially close its lumen, as desired.

When the design of Figures 12-15 is installed in the foregoing manner, the needle 28 will then be withdrawn from or retracted into the catheter 26 and a winding tool 36 will then be advanced from the catheter into contact with the windable cord 30c'. This winding tool 36 may be a hook (as shown) or any other suitable apparatus capable of twining, deforming, crimping, tying or knotting the cord 30c'--in accordance with the particular type of material of which the cord 30c' is formed (e.g., plastically deformable or pliable/knottable). This winding tool 36 is then used to wind (i.e., plastically deform, knot, twine or tie) the cord 30c' in a manner which causes the cord 30c' to shorten, thereby pulling the engagement members 30a', 30b' inwardly to cause the wall of the anatomical structure 34 to collapse and its lumen to become fully or partially closed, as desired. As will be recognized, the winding tool 36 may then be disengaged from the wound cord 30c' and removed, or alternatively may be designed to be detached from the catheter 26 and left in place within the wound cord 30c'. In this regard, the winding tool 36 may be configured to detach from the catheter 36 by separation of a weakened "tear away" area formed in the tool 36 such that the distal portion of the tool 36 will break away when sufficient proximally directed or rotational force is applied thereto. In this respect, it will be recognized that the force necessary to break winding tool 36 will be less than the force necessary to dislodge the hook member 36 from the attachment cord 30c' that is wrapped thereabout.

iii. Third Embodiment--Twist Clip Apparatus

Referring now to Figures 16 and 17, there is shown a third embodiment on an intraluminal apparatus for occluding blood flow at a specific site within a luminal anatomical structure such as a blood vessel. As shown in Figure 16, third embodiment may comprise an elongate rigid or pliable catheter 38 having a hollow lumen extending longitudinally therethrough and a side opening 38a formed near its distal end. Disposed within the lumen of the catheter 38 is a twist clip 42. The twist clip 42 is formed of malleable material and comprises a first straight section 42a and a second section 28b, which extends generally perpendicular to the first straight section 42a. An outwardly curved tip 42c is formed on the distal end of the second section 42b. As illustrated, the twist clip 42, and more particularly the outwardly curved tip 42c thereof, is initially advanced some distance out of the side opening 38a and to pierce through the vessel wall 40. Thereafter, the catheter 38 is rotated, as indicated by the arrow on Figure 14, so that the clip 42 advances fully or partially around the wall of the anatomical structure 40 to cause its lumen to become fully or partially closed, as shown in Figure 17. By virtue of the shape of the outwardly curved tip 42c, the clip 42 is thus secured to the outside of the wall while simultaneously forming an intraluminal closure. After such intraluminal closure is formed, the catheter 38 is axially retracted through the lumen of the anatomical structure 40, causing the twist clip 42 to detach and remain embedded within or about the wall of the anatomical structure 40, as shown. As will be recognized, twist clip 42 may be configured to detach from catheter 38 by forming a weakened or break-away area in the clip such that the clip 42 will break away when sufficient proximally directed or rotational force is applied thereto. In this respect, it will be recognized that the force necessary to break twist clip 42 free from the catheter 38 will be less than the tension necessary to dislodge the clip 42 from the wall of the anatomical structure 40.

iii. Fourth Embodiment--Intraluminal Suturing Device

Figures 18-22b are directed to an intraluminal suturing device 50, 50' having an inboard penetrating member 54, 54', and Figures 23a-26 are directed to an alternative intraluminal suturing device 50" having an outboard penetrating member 530. These intraluminal suturing devices may be used to repair tears or ruptures in anatomical conduits, to occlude anatomical conduits (*see*, Figures 19a-19b described herebelow), to anastomose or join approximated segments of anatomical conduit (*see*, Figure 18a (line AN) and/or Figures 28a-29b described

herebelow) or to anchor or attach various articles (e.g., an endovascular graft) to the wall of an anatomical conduit (*see*, Figures 20, 27a and 27b described herebelow).

a. Inboard Needle Type:

As shown in Figures 18-21d and 22-22c, these devices 50, 50' generally comprise an elongate pliable catheter body 52, 52' having a proximal end PE, a distal end DE, and a hollow lumen 54, 54' which extends longitudinally therethrough. A side opening 56, 56' is formed on one side of the catheter body 52, 52' near the distal end DE thereof. A balloon 58, 58' or other suitable type of lateral pressure exerting member (e.g., an extendable foot) may optionally be mounted on the outer surface of the catheter body 52, 52' at a location which is substantially diametrically opposite the location of the side opening 56, 56'. An axially moveable needle advancement/retraction member 64, 64' is mounted within the lumen 54, 54' of the catheter body 52, 52'. A tissue penetrating member such as a needle, 74, 74' is mounted within the lumen 54, 54' of the catheter body 52, 52' and is axially moveable back and forth, by way of the needle advancement/retraction member 64, 64'. The needle 74, 74' is reciprocally moveable back and forth between i) a first position wherein the needle 74, 74' is proximal to the side opening 56, 56', and ii) a second position wherein the needle 74, 74' is distal to the side opening 56, 56'.

A first portion of the wall of the luminal anatomical structure (e.g., blood vessel) wherein the catheter body 52, 52' is positioned may be drawn or otherwise caused to intrude (e.g., invaginate, lapse) into the side opening 56, 56' such that the needle 74, 74' may be advanced or retracted through the intruding portion of tissue. In this manner, a length of connector material 88, 88' such as suture thread, which is attached to the needle 74, 74', will be drawn through the intruding tissue to form a stitch in the wall of the luminal anatomical structure. In embodiments wherein the suture line is to be used to close or occlude the anatomical structure, the a continuous suture 88, 88" will be passed through multiple locations about the wall of the anatomical structure and the suture 88, 88' will be drawn taught in the nature of a "purse string", thereby collapsing the wall of the anatomical structure inwardly and causing its lumen to become fully or partially closed, as desired. In other applications, wherein the suture material 88, 88' is to be used to attach or anchor an article or apparatus (e.g., an endoluminal tube graft) to the wall of the luminal anatomical structure, such article or apparatus will be pre-positioned adjacent the wall of the anatomical structure and the intraluminal suturing device will be used to place continuous or interrupted stitches through the article/apparatus and the wall of the anatomical structure, so

as to anchor the article/apparatus to the anatomical structure as desired.

In the particular embodiment shown in Figures 18-18a the needle advancing/retracting member 64 comprises an elongate shaft 66 having a bifurcated, generally "C" shaped distal portion 68. This C-shaped distal portion 68 comprises a generally "C" shaped member 70 having first and second needle abutting indentations 72a, 72b formed on its directly opposing ends, as shown. A cross-member 60 is formed within or attached to the tubular catheter body 52 on opposite side thereof, such that the cross-member 60 traverses the lumen 54 of the catheter at a location directly beneath the side opening 56. An indentation 62 is formed in the upper surface of the cross-member 60 immediately beneath the side opening 56. The "C" shaped distal portion 68 of the needle advancing/retracting member 64 partially surrounds the cross-member 60, as shown. A dual-tipped needle 74 is mounted within the lumen 54 above the cross-member 60. Needle abutting surfaces 72a, 72b of the C-shaped portion 68 of the needle advancing/retracting member 64 are preferably of a concave shape so as to axially receive the sharpened ends of the needle 74. In this manner, when the needle advancing/retracting member 64 is advanced in the distal direction, the first needle abutting surface 72a will push the needle 74 past the side opening 56 and to an advanced position distal to the side opening 56, but still within the lumen 54 of the catheter body 52. Thereafter, when the needle advancing/retracting member 64 is retracted in the proximal direction, the second needle abutting surface 72b will drive the needle 74 in the proximal direction, past the side opening 56, and to a retracted position which is proximal to the side opening 56, but still within the lumen 54 of the catheter body 52.

A proximal connector assembly 80 may be mounted on the proximal end PE of the catheter body 52. Such proximal connector assembly 80 incorporates a slidable actuator knob 82 which is connected to the needle advancing/retracting member 64 such that when the actuation knob 82 is advanced in the distal direction, the needle advancing/retracting member 64 will advance in the distal direction, and when the actuation knob 82 is retracted in the proximal direction, the needle advancing/retracting member 64 will retract in the proximal direction. Additionally, the preferred proximal connector assembly 80 may have a balloon inflation port 84 connected to a balloon inflation lumen 89 which extends longitudinally through the catheter body 52 and which terminates distally in the interior of the balloon 58. In this manner, balloon inflation fluid may be injected and withdrawn through the balloon inflation port 84 to effect inflation and deflation of the balloon 58, as desired. A suture passage aperture 75

is formed vertically through the cross-member 60 at a location immediately beneath the center of the side opening 56 and the strand of suture material 88 which extends into the proximal port of the proximal connector assembly 80 continues through the suture lumen 53 of the catheter body, upwardly through the suture passage aperture 75 formed in cross-member 60, and is
5 attached to the dual tip needle 74 at a location between the opposite sharpened ends of the needle 74, and preferably at the approximate longitudinal mid-point of the needle 74.

The device of Figures 18-18a may be utilized to place suture(s) in the wall of a blood vessel by inserting the pliable catheter body 52 into the patient's vasculature and advancing the catheter body 52 through the vasculature until the side opening 56 is located at the site at which
10 the first stitch is to be placed. In some instances, the diameter of the catheter body 52 will be as large as the inner diameter of the blood vessel lumen such that a portion of the blood vessel wall will automatically intrude into the side opening of the catheter body. In other instances, the diameter of the catheter body 52 will be less than the inner diameter of the blood vessel and the side balloon 58 will be used to compress the catheter laterally against the wall of the vessel. In
15 this regard, a syringe may be attached to the balloon inflation port 84 and utilized to infuse a balloon inflation fluid (e.g., saline solution) into the balloon 58 to inflate the balloon 58. The inflated balloon 58 will contact the wall of the vessel and will propel the catheter body 52 laterally against the wall of the vessel opposite the location of the balloon 58. In this manner, the side opening 56 will become compressed against the blood vessel wall BVW and a portion
20 of the tissue of the blood vessel wall BVW will intrude (e.g., invaginate or lapse) into the side opening 56 and into the lumen 54 of the catheter into the path of the needle 74. To facilitate such intrusion of the blood vessel wall BVW into the side opening 56 suction may optionally be applied to the lumen 54 of the catheter body.

After the blood vessel wall BVW has been caused to intrude inwardly into the side
25 opening 56, the operator will advance the actuator knob 52 in the distal direction so as to cause the needle advancing/retracting member 64 to also advance in the distal direction. In this manner, the first needle abutting surface 72a of the needle advancing/retracting member 64 will abut against the first sharpened end of the needle 74 and will drive the needle in the distal direction, through the portion of the blood vessel wall BVW which intrudes into the lumen 54
30 of the catheter body 52. After the needle 74 has been fully advanced through the intruding tissue of the blood vessel wall BVW, the balloon 58 may be deflated (if used) and any optional suction

will be terminated. Thereafter, the catheter body will be repositioned (e.g., rotated slightly and/or moved longitudinally) so that the side opening 56 becomes positioned next to a second location on the blood vessel wall BVW. The balloon 58 may be once again inflated (if necessary) so as to press the side opening 56 of the catheter body 52 laterally against the second location on the blood vessel wall BVW, and any optional suction may be applied so as to cause another portion of the blood vessel wall BVW to intrude inwardly into the side opening 56. Thereafter, the operator will retract the actuator knob 82 so as to cause the needle advancing/retracting member 64 to retract in the proximal direction driving the needle 74 in the proximal direction, through the second portion of the blood vessel wall BVW which has been caused to intrude inwardly through the side opening 56. After the needle 74 has been fully advanced through such intruding tissue, the balloon 58 will be once again deflated (if used) and any optional suction will be terminated. Thereafter, the catheter body 52 may again be repositioned, and the above-described procedure repeated as many times as necessary to form the desired suture line in the blood vessel wall BVW. After the desired stitch or suture line has been installed, the device 50 may be retracted and a knot pusher of the type commonly used in laparoscopic surgery may be utilized to form a tie or knot in the suture material 88. In applications wherein it is desired to use the suture material 88 to draw the lumen of the blood vessel closed, the suture 88 may be pulled taught in a purse string fashion, so as to collapse and close the lumen of the blood vessel in the manner shown in Figure 19b. In other applications, the suture material may be interrupted or continuous and may be tied off or knotted using the knot pusher, without drawing the lumen of the blood vessel closed. This procedure may be used to form a radial purse string closure or anastomosis in a blood vessel as shown in Figures 19-19a. Alternatively, this procedure may be used to anchor an article or apparatus, such as an endoluminal graft 90 for bridging of an aneurism AN, as shown in Figure 20. The procedure illustrated in Figure 20 may offer advantages over prior art methods wherein endoluminal grafts were held in place or anchored by way of a radially expandable stent for frictional engagement of the graft 90 to the blood vessel wall BVW. In this regard, the intraluminal suturing devices 50, 50', 50" may be used to sew the opposite ends of a pliable tube graft (e.g., woven polyester or expanded polytetrafluoroethylene (ePTFE)) to the blood vessel wall BVW so as to anchor and hold the tube graft 90 at its desired position, without the need for radially expandable stents or other hardware required for frictionally engaging or anchoring the graft 80 to the blood vessel wall BVW.

Figures 22, 22a, and 22b show a variation of the above-described fourth embodiment wherein the intraluminal suturing device 50' has a modified catheter body 52' which has a proximal end PE, a distal end DE, a main lumen 54' extending longitudinally therethrough. A side opening 56' is formed into the main lumen 54' at a first location on one side of the catheter body 52', and an optional balloon 58' may be formed on the catheter body 52' at a location diametrically opposite the side opening 56'. As in the above-described fourth embodiment, a balloon inflation lumen 89' extends longitudinally through the catheter body 52' to permit inflation fluid to be infused into and withdrawn from the balloon 58'. In this variation, the needle advancing/retracting member 64' has a sharpened distal tip 67. A first needle connector is formed on the needle advancing/retracting member 64' near its distal end 67 and a corresponding second needle connector (e.g., a notch) 102 is formed adjacent the proximal end of the needle 74'. Additionally, needle holding members 108 are formed within the main lumen 54' of the catheter body 52' at a position distal to the side opening 56', such needle holding members 108 being constructed to frictionally engage and prevent rotation of the needle 74' while in its second position distal to the side opening 56'. The suture material 88' is attached to the needle 74' at a location between its proximal end 107 and distal end 106, and preferably at the approximate mid-point of the needle 74'.

When this variation of the fourth embodiment shown in Figures 22, 22a, 22b is used to place sutures in a blood vessel, the catheter body 52' will be advanced transluminally through the vasculature until the side opening 56 is positioned at the site at which it is desired to place sutures through the wall of the blood vessel. Thereafter, the balloon inflation fluid may be infused (if needed) through the balloon inflation lumen 89' to inflate the balloon 58', thereby compressing the side opening 56' against a first location on the blood vessel wall in a manner which causes the blood vessel wall to intrude into the main lumen 54'. Optionally, suction may be applied to the main lumen 54' to draw the tissue inwardly through the side opening 56'. Thereafter, the needle advancing/retracting member 64' is advanced in the distal direction so as to drive the needle 74' through the portion of the blood vessel wall which has been drawn through the side opening 56' and to its second position located distal to the side opening 56'. After the needle has been advanced to such second position, the needle holding members 108 will frictionally engage and prevent rotation of the needle, and the needle advancing/retracting member 64' will be slightly rotated so as to disengage the first and second needle connectors

100, 102 from each other, thereby releasing the needle advancement/retraction member 64' from the needle 74'. Thereafter, the needle advancing/retracting member is withdrawn proximally to a position proximal to the side opening 56'. Thereafter, the balloon 58' is deflated (if previously inflated), and the catheter body 52' is repositioned such that the side opening 56' is positioned
5 adjacent a second location on the blood vessel wall. Thereafter the balloon 58' is once again inflated (if necessary) and any optional suction desired may be applied to the main lumen 54' so as to draw a second portion of the blood vessel wall into the main lumen 54' through the side opening 56'. Thereafter, the needle advancing/retracting member 64' is advanced in the distal direction such that the sharpened distal tip 67 of the needle advancing/retracting member 64' will
10 pass through the intruding tissue. After the needle advancing/retracting member 64' has been advanced until its needle connector 100 is located in alignment with the needle connector 102 formed on the proximal end of the needle 74', the needle advancing/retracting member 64' will be slightly rotated so as to engage its needle connecting member 100 with that 102 of the needle 74', thus reconnecting the advancing/retracting member 64' to the needle 74'. Thereafter, the
15 needle advancing/retracting member 64' is again withdrawn in a proximal direction so as to pull the needle 74' back through the tissue and to its first position wherein the needle 74' is positioned proximal to the side opening 56'. Thereafter, the above-described steps are again repeated as many times as necessary to form the desired stitch or suture line in the blood vessel wall.

After the desired stitch or suture line has been placed in the wall of the blood vessel, the
20 catheter 52' may be removed and the suture may be drawn closed so as to ligate the blood vessel, or otherwise tied or knotted to anchor or affix an article or apparatus to the wall of the blood vessel, as described in detail hereabove.

b. Outboard Needle Type:

Figures 23a-26 show another intraluminal suturing device 50''' of the present invention,
25 which incorporates an "outboard" tissue penetrating member or needle 530 that extends out of the catheter body 502 so as to pass connector material such as suture thread 529 through the wall of a luminal anatomical structure, such as a blood vessel, within which the catheter body 502 is inserted. In this manner, this device 50''' does not require that any portion of the wall of the luminal anatomical structure be caused to intrude into the catheter body, as with the above-
30 described inboard needle embodiments of the device 50, 50''.

As shown, this device 50''' comprises an elongate, rigid or pliable, catheter body 502

having an irregularly shaped main lumen 504 formed within a distal portion of the catheter body 102. In the embodiment shown, the main lumen 502 is generally of an hourglass or dumbbell cross-sectional shape which defines an upper portion 506, a lower portion 508 and a communicating channel 510 which extends between the upper portion 506 and the lower portion 508. This main lumen 504 is formed in its entirety only in a distal portion of the catheter body 502 and all portions of the main lumen 504 terminate distally in a closed distal end 505. The upper portion 506 and the communicating channel 510 terminate proximally in a closed proximal end 507 within the catheter body 502, but the lower portion 508 continues through the proximal end of the catheter body 502 and through a proximal opening (not shown).

A needle outlet branch lumen 516 extends from the upper portion 506 of the main lumen 504 and through a first opening formed in the side of the catheter body 502. A needle inlet branch lumen 518 extends from the upper portion 506 of the main lumen 504 to a second opening formed in the side of the catheter 502 distal to, and preferably in alignment with, the first opening. Also, an arcuate dip AD may be formed in the portion of the main lumen 504 which passes between the needle outlet branch lumen 516 and the needle inlet branch lumen 518. Additionally, as shown in Figure 24b, a suture passage slit 511 is formed longitudinally in the portion of the catheter body 502 located between the needle outlet branch lumen 516 and the needle inlet branch lumen 518. Such slit 511 provides a narrow suture passage channel which extends downwardly from the upper surface of the catheter body 502 into the upper portion 506 of the main lumen 504.

A preformed resilient penetrating member, such as a curved needle 530 is slidably disposed, in a straightened configuration, within the upper portion 506 of the main lumen 504. As shown in Figure 26, the preferred needle 530 has a straight shaft SH, a curves segment CS on the distal end of the straight shaft SH, a straight segment SS on the distal end of the curved segment CS, and a sharpened distal tip DT.

A needle advancing/retracting member 520 of the type shown in Figures 25 and 25a is slidably disposed within the catheter body 502 and is used to alternately advance and retract the needle 530, as will be described in more detail herebelow. The preferred needle advancing/retracting member 520 comprises and elongate shaft 528 having a clip 524 disposed on its distal end, and a control knob 522 on its proximal end. The control knob 522 is coupled to the clip 524 by way of a mechanical linkage (not shown) which extends through the shaft 528.

The clip 524 comprises first and second laterally extending arms 526a, 526b, the ends of which are pivotally attached to a linkage hub 528. The clip resides slidably within the main lumen 504 of the catheter 502, with the hub disposed in the lower portion 508 and the arms 526a, 526b extending through the connecting channel 510 and into the upper portion 506, on either side of the needle 530, such that the needle 530 may be captured and grasped between the distal ends of the arms 526a, 526b. The shaft 528 of the needle advancing/retracting member 520 extends proximally through the lower portion 508 of the lumen and extends out of the proximal lumen opening (not shown) such that the control knob 522 is accessible to the operator during the procedure.

A length of connector material, such as suture thread 528 is connected to the proximal end of the needle 530 and extends through the proximal segment of the lower lumen portion 508, along side the shaft 528 of the needle advancing/retracting member 520.

In routine operation, the catheter 502 is advanced, distal end first, through the body and the first and second openings which communicate with the needle outlet branch lumen 516 and needle inlet branch lumen 518 are positioned adjacent a first location on the wall of a luminal anatomical structure such as a blood vessel. As shown in Figure 23a, the needle 530 is initially positioned within the upper lumen portion 506, proximal to the location at which the needle outlet branch lumen 516 diverges therefrom. Also, as shown in Figure 23a, the needle advancing/retracting member 520 is initially positioned and deployed such that its arms 526a, 526b are grasping the needle 530 near its proximal end.

Thereafter, as shown in Figure 23b, the needle advancing/retracting member 520 and needle 530 are advanced in the distal direction. The distal tip of the needle is configured or biased to automatically advance into the needle outlet branch lumen 516 and out of the first outlet opening as shown.

As shown in Figure 23c, the needle advancing/retracting member 520 and needle 530 are further advanced such that the needle will penetrate fully or partially through the tissue of the wall of the luminal anatomical structure. As it advances out of the catheter 502 and through the tissue, the resilient needle 530 will assume its preformed configuration as shown in Figure 26. This preformed shape of the needle 530 causes its distal end to reenter the catheter 502 through the needle inlet branch lumen 518, as shown in Figure 23c. The needle inlet branch lumen 518 may be chamfered or tapered such that it is largest in diameter at the second opening in the side

of the catheter and progressive narrows as it extends inwardly, thereby enhancing the ability of the distal tip DT of the needle 530 to locate and pass into the needle inlet branch lumen 518 in the manner shown.

5 Referring to Figure 23d, the control knob 522 is then rotated in the direction which causes the arms 526a, 526b to pivot away from each other, thereby releasing the needle from the grip of the clip 524. As shown in Figure 24b the communicating channel 510 of the lumen 504 is wide enough and preferably somewhat tapered, to allow the arms 526a, 526b of the clip 524 to separate sufficiently to release the needle 530 from the grip of the clip 524.

10 In the manner shown in Figure 23d, the needle advancing/retracting member 520 is then advanced further in the distal direction until the clip 524 becomes positioned adjacent the distal end of the needle (e.g., at the junction of the main lumen 504 and the needle inlet branch lumen 518). The control knob 522 is then rotated in the direction which causes the arms 526a, 526b of the clip to pivot toward each other so as to capture and grasp the distal end of the needle 530 therebetween.

15 As shown in Figure 23 e, the needle advancing/retracting member 520 is then further advanced in the distal direction until the clip 524 abuts against the distal end 505 of the main lumen 504 and the proximal end of the needle 530 has been pulled into the distal portion of the lumen 504 with the suture thread 529 in tow.

20 Thereafter, as illustrated in Figure 23f, the control knob 522 is rotated to loosen the clip 524 and release the needle 530, and the needle advancing/retracting member 520 is retracted in the proximal direction until the clip becomes repositioned adjacent the proximal end of the needle 530.

25 Thereafter, as shown in Figure 23g, the control knob 522 is rotated to tighten the clip 524 so that it once again grips the needle 530 and the needle/advancing/retracting member is then further withdrawn in the proximal direction.

As shown in Figure 23h, the needle advancing/retracting member 520 is withdrawn in the proximal direction until the needle 530 has returned to its starting position. The suture thread 529 is concurrently pulled through the slit 511 such that the needle 530 and suture thread 529 are then prepared to repeat the above summarized steps shown in Figures 23a-23h.

30 The catheter may be rotationally and/or longitudinally repositioned, and the above summarized steps may be repeated, as necessary to form the desired number of stitches in the

wall of the anatomical structure. One or more knots may be placed in the suture thread 629 to secure the stitch(es) using an appropriate knot-pusher device of the type known in the art and used in various endoscopic or port-access surgical procedures.

**v. Fifth Embodiment—Device Useable to Form Attachments
to, or Anastomoses in, a Luminal Anatomical Structure**

Figures 27-27c show another device 200 which utilizes attachment member(s) 208 having a structure similar to T-Occluder device 30 shown in figures 7-11 and described hereabove. This device 200 comprises a transluminal catheter 202, which may be of rigid or pliable construction, and a slotted, hollow needle 204 which is advancable out of the catheter 202. In the particular embodiment shown, the slotted, hollow needle 204 is formed of resilient or superelastic material, and is biased to a curved configuration, such that the distal portion of the needle 204 will assume a curved configuration as it is advanced out of a distal end opening 220 of the catheter 202. In this manner the sharpened distal tip 214 of the needle 204 will puncture fully or partially through the wall of the anatomical conduit (e.g., blood vessel) within which the distal end of the catheter 202 is positioned. It will be appreciated, however, that various other catheter/needle designs may be employed wherein the needle 204 may be deflected or otherwise caused to exit the catheter through an opening in the side of the catheter 202, rather than through the distal end thereof. The preferred needle 204 is constructed to carry a plurality of attachment members 208 and to facilitate the installation of those attachment members 208 in the wall of a luminal anatomical structure (e.g., a blood vessel). In this regard, the elongate slot 210 is preferably formed only on one side of a distal portion of the needle 204, such that the proximal shaft of the needle remains in tact and unslotted. One or more of these attachment members 208 are loaded into the lumen of the needle 204 in the manner shown in Figure 27. Each attachment member 208 comprises a pliable link 212 formed of suture thread, a pliable filament, a strand of plastic, or other suitable material. Engagement members 209 are formed upon opposite ends of each link 212. In the particular embodiment shown, the engagement members 209 are in the nature of cross members, each such cross member having a longitudinal axis LA-T which is substantially perpendicular to the longitudinal axis LA-L of the link 212. In some embodiments, the engagement members will be coupled to one another in a chain-like fashion, while they remain loaded in the lumen of the needle 204, but each such engagement member 209 will become uncoupled from its neighboring engagement member 209 when it is expelled out of the distal tip 214 of the needle 204. With respect to the particular cross member-type engagement members 209 shown in

Figures 23-23c, each such engagement member 209 has a first connector 230 formed on one end thereof, and a second connector 232 formed on the other end thereof. The first connector 230 of one engagement member 209 is connected to, but disconnectable from, the second connector 232 of a neighboring engagement member 209 within the lumen of the needle 204. This chaining or linking of the engagement members 209 allows them to be moved longitudinally in unison so long as they are sequentially packed in the lumen of the needle 204. However, when one engagement member 209 is expelled from the needle 204 and caused to assume an orientation which is non-coaxial to and/or not in end-to-end alignment with its neighboring engagement member 209, the second connector 232 of that engagement member 209 will disconnect and separate from the first connector 230 of the neighboring engagement member 209. In this manner the next neighboring engagement member 209 remains within the lumen of the needle 204, and remains coupled to any subsequent engagement members 209 which are also within the needle lumen, as illustrated in Figure 23. The connectors 230, 232 formed on the engagement members 209 may be constructed and configured in many suitable ways, and may create various types of suitable interconnections (e.g., mechanical, frictional, adhesive, magnetic, etc.). In the particular embodiment shown, the first connector 230 of each engagement member 209 comprises a first notch 234 having a receiving aperture 236 associated therewith, and the second connector 232 of each engagement member 209 comprises a second notch 238 having a raised projection 240 (e.g., a lug, post, tongue, boss, etc.) associated therewith. The second connector 232 of one engagement member 209 is received within the receiving aperture 236 of the first connector 230 of the neighboring engagement member 209, so as to couple or link those engagement members 209, while they remain in sequential, contiguous alignment within the lumen of the needle 204. The links 212 of these interconnected attachment members 208 protrude, in looped fashion, out of the slot 210 of the needle 204, as shown.

An ejector/retraction member (not shown) is passed through the lumen of the needle 204, proximal to the proximal-most engagement member 209 loaded into the lumen of the needle. Such ejector/retraction member is connected to or grasps the proximal-most engagement member, and is useable to selectively expel one engagement member 209 at a time from the distal tip 214 of the needle 204. In operation, the catheter 202 is inserted and advanced transluminally until the distal end of the catheter 202 is positioned in the lumen of a luminal anatomical structure, at the location where an anastomosis or attachment is to be made. The needle 204 is then advanced out of the distal end aperture 220 of the catheter 202 until the sharpened

distal tip 214 of the needle has punctured fully or partially through the wall of the luminal anatomical structure. Thereafter, the ejection/retractor member (not shown) is advanced in the distal direction to expel the first (i.e., distal-most) one of the engagement members 209 out of the end of the needle 204. As the first engagement member 209 passes out of the end of the
5 needle 204 the force exerted by its link 212 will cause that engagement member 209 to assume an orientation which causes its second connector 323 to become uncoupled from the first connector 230 of the next engagement member 209. The ejection/retractor member may then be retracted in the proximal direction to pull any protruding portion of the next engagement member 209 back into the lumen of the needle 204. In this manner, the first expelled engagement member
10 209 is deployed outside of the luminal anatomical structure such that it will abut against or engage the outer surface of the luminal anatomical structure (e.g., the adventitial surface or layer of a blood vessel) as illustrated in Figures 23 a, b and c. The needle 204 is then retracted into the catheter 202, and the catheter 202 is repositioned (i.e., moved longitudinally and/or rotated) such that the needle 204 becomes aimed at a second location on the wall of the luminal anatomical
15 structure. The needle is then readvanced through the wall of the luminal anatomical structure and the above-described procedure repeated to place the second engagement member 209 at a second location outside of the luminal anatomical structure, with the link 212 which joins those two engagement members 209 traversing through the lumen of the anatomical structure. This entire procedure may then be repeated one or more times until the desired suture line or row(s) of
20 attachment members 208 have been installed to form the desired attachment or anastomosis. In at least some applications, the engagement members 209 will be initially loaded into the lumen of the needle 204 in a chain like fashion and all of the engagement members 209, except for those on either end of the chain, will have two (2) links connected thereto, as shown in the figures. This will cause the engagement members to form a continuous suture line, attachment
25 or anastomosis in the wall of the luminal anatomical structure. 30 This device 200 may be used for many purposes, including a.) attaching or anchoring an endoluminal graft, stent or other item/apparatus to the luminal anatomical structure, b.) connecting the luminal anatomical structure to another anatomical structure, or c.) forming an anastomotic junction between the luminal anatomical structures and another anatomical structure or between two
30 approximated cut ends of the same luminal anatomical structure (as may occur following transection or resection of that luminal anatomical structure). Figures 23a and 23b specifically illustrate one way in which this device may be used to anchor the end(s) of a tubular endoluminal

graft 300 to the wall of a blood vessel BV. As shown in Figures 27a and 27b, the tubular graft 300 is placed within the lumen of the blood vessel BV at a desired location (e.g., such that it extends through an aneurysmic, diseased or injured portion of that blood vessel BV). The catheter 202 is then advanced into the luminal anatomical structure and positioned such that the outlet opening 220 at the distal end of the catheter is adjacent one end of the graft 300. A series of the attachment members 208 are then installed, in an annular array, to anchor that end of the graft 300 to the wall of the blood vessel BV. The same procedure may then be repeated to anchor the other end of the tube graft 300 as well. In this manner, the graft 300 is firmly held in place and prevented from migrating within the blood vessel. In applications wherein it is desired to have the end(s) of the graft 300 held tightly against the wall of the blood vessel BV to prevent blood from seeping into or entering the space between the outer surface of the graft and the wall of the blood vessel (e.g., an "endoleak"), the links 212 of the attachment members 208 may be formed of elastic material to accomplish such tight approximation of the graft, or the links 212 may be formed of malleable material and twisted or deformed to a shortened configuration to pull the graft tightly against the blood vessel wall. Alternatively a sealing substance (e.g., a biologically compatible adhesive) or space-occupying members (e.g., embolization coils, beads, gelfoam, etc.) may be applied or deposited about the end(s) of the graft 300 to prevent such leakage of blood around the graft.

Figure 27c shows another possible application wherein the device 200 is used to form an end to end anastomosis between transected ends TE of an anatomical conduit AC such as a blood vessel, duct, tube or passageway of the body. In this application, the engagement members 209 are installed in a staggered radial array (i.e. a zig-zag array around the anastomotic junction) so as to connect the transected ends TE of the anatomical conduit AC in abutting approximation and the desired alignment. Such staggered positioning of the engagement members 209 may be accomplished by longitudinally advancing and retracting the catheter, back and forth, in conjunction with each incremental rotation thereof, to cause the engagement members 209 to be installed around, and on opposite sides of, the anastomotic junction, as shown in Figure 27c.

Figure 27d shows another possible application wherein a device similar to that shown in Figure 27 has been used to install a series of interrupted attachment members 208' to form an end-to-side anastomosis between two anatomical conduits. These interrupted attachment members 208' differ from the continuous attachment members 208 shown in Figures 27-27c in a single link portion 212' is connected to each engagement member 209', rather than having some

engagement members 209 which have two link portions 212 of adjacent attachment apparatus 209 both connected thereto. Those skilled in the art will understand that, in this manner, these attachment apparatus 208' are installed in an interrupted rather than continuous fashion.

Those skilled in the art will further understand and appreciate that the devices 5, 50', 50", 50''' and 200 which have been disclosed hereabove as being useable to form anastomotic junctions between two (2) anatomical conduits or two (2) segments of the same anatomical conduit, may be used to form numerous types of anastomotic junctions, and will not be limited to only the end-to-end type junctions specifically shown in Figures 18 or 27c. Rather, these devices 50, 50', 50", 50''' or 200 may additionally be used to form end-to-side junctions as illustrated schematically in figures 28a & 28b, and/or side-to-side junctions as illustrated schematically in Figures 29a & 29b.

It is to be further appreciated and understood that the invention as been described hereabove with reference to certain presently preferred embodiments or examples only, and no attempt has been made to exhaustively describe all possible embodiments or examples in which the invention may be practiced, or take physical form. Indeed, various additions, deletions, modifications, and alterations may be made to the above-described embodiments and examples without departing from the intended spirit and scope of the invention. Accordingly, it is intended that all such additions, deletions, modifications, and alterations be included within the scope of the following claims.

20

WHAT IS CLAIMED IS:

1. A device for fully or partially closing the lumen of an anatomical structure, said anatomical structure having a wall and a lumen which is substantially defined by said wall, said device comprising:

5 a closure member which is advancable from a position within the lumen of the anatomical structure, at least partially through its wall, said closure member being configured to engage the wall of the anatomical structure, and said closure member being biased to a closed configuration whereby it will cause the wall to collapse inwardly in a manner which at least partially closes the lumen of the anatomical structure.

10 2. The device of Claim 1 wherein the device further comprises:

an elongate piercing member which is useable to penetrate at least partially through the wall of the anatomical structure, said piercing member having a sharpened distal end, a hollow bore, and an outlet opening which is in communication with its bore;

15 at least one of said closure members being initially disposed within the bore of the piercing member and advanceable out of the outlet opening of the piercing member, after said piercing member has been penetrated at least partially through the wall of the anatomical structure, such that said closure member will then engage the wall of the anatomical structure and cause the wall of the anatomical structure to collapse inwardly in accordance with Claim 1.

20 3. The device of claim 2 wherein said piercing member is removable from the body after said at least one closure member has been passed therefrom, such that said at least one closure member will remain implanted within the anatomical structure to at least partially close the lumen of the anatomical structure.

4. The device of Claim 2 further comprising:

25 an elongate pliable catheter having said piercing member disposed therewithin, said catheter being transluminally advancable into the lumen of said anatomical structure and said piercing member being thereafter advanceable out of said catheter to penetrate at least partially through the wall of the anatomical structure in accordance with Claim 2.

5. The device of Claim 1 wherein said closure member comprises:

30 a resilient, elongate member which is biased to a coiled configuration, at least a portion of said elongate member being advancable at least partially through the wall of the anatomical structure, said elongate member having at least one engagement member formed thereon to

engage the wall of the anatomical structure;

the coiled configuration to which said resilient, elongate member is biased being operative to draw the wall of the anatomical structure inwardly to at least partially close the lumen of the anatomical structure.

5 6. The device of Claim 5 wherein said elongate member is formed of malleable material.

7. The device of Claim 5 wherein said at least one engagement member comprises a barb.

8. The device of Claim 5 wherein said at least one engagement member comprises a hook.

10 9. The device of Claim 5 wherein said at least one engagement member is a projection.

10. The device of Claim 5 wherein said at least one engagement member is a cross member.

11. The device of Claim 4 wherein said piercing member is formed of resilient material which will assume a substantially straightened configuration when retracted within the catheter, but which will assume a curved configuration when advanced out of catheter.

12. The device of Claim 1 wherein:

said elongate member comprises an elongate, pliable link member having first and second ends; and wherein said at least one engagement member comprises first and second engagement members formed on the first and second ends of said link member.

13. The device of Claim 12 wherein said first engagement member is deployable into engagement with a first location on the wall of the anatomical structure, said second engagement member is deployable into engagement with a second location on the wall of the anatomical structure, and said link member is constructed to pull said first and second engagement members inwardly, thereby drawing the first and second locations on the wall of the luminal structure toward each other so as to at least partially close the lumen of the anatomical structure.

14. The device of Claim 13 wherein said link member is formed of elastic material and is elastically biased to a shortened configuration, said biasing of said link member to said shortened configuration being operative to drawing the first and second locations on the wall of the luminal structure toward each other so as to at least partially close the lumen of the anatomical structure.

15. The device of Claim 12 wherein said engagement members are barbs.

16. The device of Claim 12 wherein said engagement members are hooks.

17. The device of Claim 12 wherein said engagement members are projections.

18. The device of Claim 12 wherein said engagement members are cross members.

5 19. The device of Claim 12 wherein said link member is formed of malleable material which is plastically deformable to a shortened configuration to pull said engagement members inwardly toward one another.

20. The device of Claim 19 further in combination with a transluminally insertable deformation tool which is useable to plastically deform the malleable material of said link
10 member after said engagement members have been deployed into engagement with the first and second locations on the wall of the anatomical structure.

21. The device of claim 20 wherein said deformation tool is a hook which is useable to hook and twist said link member.

22. The device of Claim 1 wherein said closure member is a twist clip device comprising
15 a resilient member having a first portion and a second portion, the second portion of said resilient member being substantially perpendicular to its first portion, said second portion of said resilient member being advancable at least partially through the wall of the luminal structure so as to engage said wall, said resilient member being biased to a twisted configuration to draw the wall of the anatomical structure inwardly, thereby at least partially closing the lumen of the anatomical
20 structure.

23. A device for passing a connector material through the wall of a luminal anatomical structure, said device comprising:

an elongate catheter which is advancable into the lumen of the anatomical structure;

25 a tissue penetrating member which is moveably disposed within said catheter, said tissue-penetrating member being advancable in at least one direction to create a puncture tract through a portion of the wall of the luminal anatomical structure into which the catheter has been inserted;

a length of connector material attached to said tissue penetrating member so as to be drawn by the tissue-penetrating member through the puncture tract which it creates through a
30 portion of the wall of the luminal anatomical structure.

24. The device of Claim 23 wherein the catheter is pliable.

25. The device of Claim 23 wherein the catheter is rigid.

26. The device of Claim 23 wherein the connector material is selected from the group of connector materials comprising:

- a. suture thread;
- b. wire;
- c. strand of natural material;
- d. strand of synthetic material;
- e. filament of natural material;
- f. filament of synthetic material;
- g. monofilament of natural material;
- h. monofilament of synthetic material;
- i. absorbable material; and,
- j. nonabsorbable material.

27. An inboard-penetrating-member embodiment of the device of Claim 23 wherein: the catheter has a proximal end, a distal end, an outer surface, a side opening formed at a first location thereon, a tissue-receiving area formed within said catheter body and into which a first portion of the wall of the luminal anatomical structure may intrude through said side opening; and a lumen which extends through the tissue-receiving area; and,

said tissue penetrating member is moveably disposed within the lumen of said catheter so as to be passable in at least one direction through the tissue-receiving area to form a puncture tract through the portion of the wall of the anatomical structure which has been caused to intrude into the tissue-receiving area, and to thereby draw said connector material through that puncture tract.

28. The device of Claim 27 wherein said catheter further comprises; a lateral pressure-exerting member extendable laterally from the catheter to drive the catheter laterally in an opposite direction, thereby pressing the side opening of the catheter against the wall of the anatomical structure such that the first portion of the wall of the anatomical structure will intrude into the tissue-receiving area.

29. The device of Claim 27 wherein a cross-member is formed within the catheter, said cross-member extending transversely across the lumen of the catheter at a location adjacent said side opening, said tissue-receiving area being located space between said cross-member and said

side opening; and, wherein said tissue-penetrating member comprises:

a dual-tipped member having sharpened first and second ends and having said connector material attached thereto at a location between said sharpened first and second ends, said dual-tipped member being disposed within the catheter, on one side of said cross-member where said tissue-receiving area is defined, such that said dual-tipped member is axially moveable back and forth through said tissue-receiving area.

30. The device of claim 29 further comprising:

an advancing/retracting member for driving said tissue-penetrating member back and forth, said advancing/retracting member having a generally C-shaped distal portion which partially surrounds said cross-member within the catheter, said generally C-shaped distal portion having a first end which is abatable against the first end of the dual-tipped needle, and a second end which is abatable against the second end of the dual-tipped needle;

said advancing/retracting member being moveable back and forth within said catheter to drive said dual-tipped needle back and forth between:

- i) a first position wherein said dual-tipped member is positioned proximal to the tissue-receiving area; and,
- ii) a second position wherein said dual-tipped member is positioned distal to the tissue-receiving area.

31. The device of Claim 29 wherein a hollow depression is formed in said cross-member in alignment with said side opening, said hollow depression defining a portion of said tissue-receiving area such that tissue which intrudes inwardly through said side opening may extend into said depression.

32. The device of Claim 27 wherein the tissue-penetrating member is a single-tipped member having a sharpened distal end, and wherein said device further comprises:

an elongate advancing/retracting member disposed within said catheter and axially moveable to drive said tissue-penetrating member back and forth, said advancing/retracting member being alternately connectable to, and disconnectable from, said tissue-penetrating member.

33. The device of Claim 32 wherein said advancing/ retracting member has a sharpened distal end which is capable of penetrating through tissue which intrudes into said tissue-receiving area.

34. The device of Claim 30 wherein said advancing/retracting member is penetrate through tissue which intrudes into the tissue-receiving area while said tissue penetrating member is positioned in its second position, and to thereafter become connected to said tissue-penetrating member and to pull said tissue-penetrating member from its second position, through the intruding tissue, to its first position, with said connector material in tow.

35. The device of Claim 30 wherein the advancing/retracting member is attachable to the tissue-penetrating member by i.) positioning the distal end of the advancing/retracting member in juxtaposition to the tissue-penetrating member and ii.) subsequently rotationally moving advancing-retracting member in a first rotational direction, while maintaining said tissue-penetrating member in a non-rotating fixed position; and wherein said device further comprises:

least one needle-rotation-preventing member formed within the catheter lumen to maintain said tissue-penetrating member in said non-rotating, fixed position.

36. An outboard-penetrating-member embodiment of the device of Claim 23 wherein the device further comprises:

a main lumen which extends longitudinally through at least a portion of the catheter;

a first opening formed in the catheter at a first location;

a second opening is formed in the catheter at a second location, said second location being a spaced distance from said first location;

a first branch lumen formed within the catheter and extending from the main lumen to the first opening;

a second branch lumen formed within the catheter and extending from the second opening to the main lumen; and, wherein,

said tissue-penetrating member is initially positioned within the main lumen at a first position, proximal to said first opening, and is thereafter advanceable i.) out of said first opening, ii.) through a portion of the wall of the anatomical structure, iii.) into the second opening, and iv.) to a second position within the catheter, said second position being distal to said second opening.

37. The device of Claim 36 wherein:

said main lumen is formed longitudinally within a distal portion of the catheter from a location proximal to the bifurcation of said main lumen and said first branch lumen;

and, wherein,

said tissue penetrating member is a resilient member which is biased to a curved configuration, said tissue-penetrating member being advancable from said first position, through said first branch lumen, outwardly through said first opening, at least partially through the adjacent wall of the anatomical structure, inwardly through said second opening, and through said second branch lumen to its second position, the curved configuration of said tissue-penetrating member being operative to guide the tissue-penetrating member to reenter the catheter through said second opening after it has been advanced out of said first opening.

38. The device of Claim 36 wherein said tissue-penetrating member is retractable from its second position, through the main lumen of the the catheter, back to its first position.

39. The device of Claim 36 wherein said tissue-penetrating member is caused to advance and retract by way of an advancing/retraction member which extends through the catheter and which is alternately connectable to, and disconnectable from, said tissue-penetrating member.

40. The device of Claim 39 wherein said main lumen comprises:

i.) an upper lumen portion wherein said tissue-penetrating member is disposed;

ii.) a lower lumen portion which is parallel to said upper lumen portion and which extends through to the proximal end of the catheter; and,

iii.) an elongate, hollow connector channel which forms a side-to-side connection between said upper lumen portion and said lower lumen portion;

and wherein said advancing/retraction member comprises:

i.) an elongate shaft which is slidably disposed within said lower lumen portion;

ii.) a clamp which is connected to said shaft and which extends laterally from said shaft, through said connector channel, and into said upper lumen portion, said clamp being useable to alternately grasp and release said tissue-penetrating member to facilitate the advancement and retraction of said tissue-penetrating member by said advancing/retraction member.

41. A device for forming attaching articles to, or forming anastomoses in, a anatomical structure which has a wall and a lumen defined by said wall, said device comprising:
an elongate catheter which is insertable into the lumen of the anatomical structure;

an elongate tissue-penetrating member initially disposed within said catheter and subsequently advancable out of the catheter, and at least partially through the wall of the anatomical structure into which said catheter has been advanced;

5 said tissue-penetrating member having a sharpened distal tip, a lumen which extends longitudinally through at least a distal portion of the tissue-penetrating member, and an outlet opening through which matter may pass out of said lumen;

at least one attachment apparatus initially loaded into said lumen of said tissue-penetrating member, said attachment apparatus comprising an elongate, flexible link having first and second ends and first and second engagement members associated with the first and second
10 ends of said link member; said attachment apparatus being incrementally advancable out of the outlet opening of the tissue-penetrating member such that first the engagement member may be initially expelled from the tissue penetrating member to engage a first location on the wall of the anatomical structure and thereafter the second engagement member may be expelled from the tissue-penetrating member to engage a second location on the wall of the anatomical structure,
15 while said link member traverses between said first and second engagement members so as to form the desired attachment or anastomosis.

42. The device of Claim 41 wherein the engagement members of the attachment apparatus are connected in series while disposed within the lumen of the tissue penetrating member, said engagement members being thereafter advanceable, one at a time, out of the outlet
20 opening of the tissue penetrating member, such that each engagement member will become disconnected from the next engagement member, as it passes out of said outlet opening.

43. The device of Claim 42 wherein said engagement members are cross-members.

44. The device of Claim 42 wherein the link members of two attachment apparatus are concurrently connected to one engagement member, such that neighboring attachment
25 apparatus share a common engagement member, and at least two of said engagement apparatus are thereby joined together.

45. A method for fully or partially closing the lumen of an anatomical structure which has a wall and a lumen defined by said wall, said method comprising the steps of:

A. providing a closure member which is advancable from a position within the
30 lumen of the anatomical structure, at least partially through its wall, said closure member being configured to engage the wall of the anatomical structure, and said closure member being biased

to a closed configuration whereby it will cause the wall to collapse inwardly in a manner which at least partially closes the lumen of the anatomical structure;

B. positioning the closure member within the lumen of the anatomical structure;

5 C. advancing at least a portion of the closure member at least partially through the wall of the anatomical structure such that it engages the wall of the anatomical structure;

D. separating the closure member from the catheter;

E. removing the catheter and leaving the closure member in place such that the biasing of the closure member to its closed configuration causes the wall of the anatomical structure to become collapsed and the lumen of the anatomical structure to become at least
10 partially closed.

46. The method of Claim 45 wherein the closure member is initially disposed within a catheter, and wherein step B comprises:

transluminally advancing the catheter into said lumen of said anatomical structure.

15 47. The method of Claim 45 wherein the closure member is an elongate member, and wherein step C comprises:

passing one end of said elongate member through the wall of the anatomical structure.

48. The method of Claim 45 wherein the closure member comprises an elongate member having at least one engagement member extending therefrom, and wherein step C comprises:

20 advancing a portion of said elongate member through the wall of the anatomical structure so that the engagement member engages the wall of the anatomical structure.

49. A method of passing a length of connector material through the wall of an anatomical structure which has a wall, and a lumen defined by said wall, said method comprising the steps of:

25 A. providing an intraluminal device which comprises;

i.) an elongate catheter which is advancable into the lumen of the anatomical structure;

30 ii.) a tissue penetrating member which is moveably disposed within said catheter, said tissue-penetrating member being advancable in at least one direction to create a puncture tract through a portion of the wall of the luminal anatomical structure into which the catheter has been inserted; and,

iii.) a length of connector material attached to said tissue penetrating member so as to be drawn by the tissue-penetrating member through the puncture tract which it creates through a portion of the wall of the luminal anatomical structure;

5 B. positioning the catheter within the lumen of the anatomical structure;

C. passing the tissue penetrating member from the catheter, through the tissue which forms the wall of the anatomical structure, to create a puncture tract through the tissue at a first location and to draw the connector material through said puncture tract; and, thereafter,

D. retracting the tissue penetrating member into the catheter.

10 50. The method of Claim 49 wherein the method further comprises the steps of:

E. repositioning the catheter within the lumen of the anatomical structure;

F. again passing the tissue penetrating member from the catheter, and through the tissue which forms the wall of the anatomical structure so as to create a second puncture tract through the tissue at a second location and to draw the connector material through said second puncture tract; and, thereafter,

15 G. again retracting the tissue penetrating member into the catheter.

51. The method of Claim 50 wherein steps E-G are repeated at least one additional time to pass the connector material through at least a third puncture tract created at at least a third location on the wall of the anatomical structure.

20 52. The method of Claim 49 wherein the method is performed to attach an article to the wall of the anatomical structure, and wherein the method further comprises the step of:

positioning the article at a desired location adjacent the wall of the anatomical structure, and wherein the catheter-positioning of step B is performed such that the tissue-penetrating member will pass through a portion of the article as well as through the tissue of the anatomical structure wall.

25 53. The method of Claim 49 wherein said method is performed to at least partially close the lumen of the anatomical structure, and wherein said method further comprises the step of:

30 drawing the connector material taught to cause the wall of the anatomical structure to collapse and the thereby at least partially occlude the lumen of the anatomical structure.

54. The method of Claim 49 wherein said method is performed for the purpose of

forming an anastomotic junction between two segments of said anatomical structure, and wherein said method further comprises the step of:

approximating the two segments of said anatomical structure and causing the first and second locations to be positioned such that the connector material will form an anastomosis between the approximated segments of said anatomical structure.

55. A method for forming an attachment to, or anastomosis in, the wall of the anatomical structure by placing at least one attachment apparatus in the wall of the anatomical structure, said method comprising the steps of:

A. providing an intraluminal device which comprises:

i.) an elongate catheter which is insertable into the lumen of the anatomical structure;

ii.) an elongate tissue-penetrating member initially disposed within said catheter, said tissue-penetrating member being subsequently advancable from the catheter and at least partially through the wall of the anatomical structure into which said catheter has been advanced, said tissue-penetrating member having a lumen which extends longitudinally through at least a distal portion of the tissue-penetrating member, and an outlet opening formed in communication with said lumen; and,

iii.) at least one attachment apparatus initially loaded into the lumen of the tissue-penetrating member, said attachment apparatus comprising an elongate, flexible link having at least first and second engagement members associated with opposite ends thereof, said attachment apparatus being incrementally advancable out of the outlet opening of the tissue-penetrating member such that the first engagement member will engage the wall of the anatomical structure at a first location and the second engagement member will engage the wall of the anatomical structure at a second location and said link(s) will extend therebetween to form the desired attachment or anastomosis;

B. positioning the catheter within the lumen of the anatomical structure;

C. advancing the tissue penetrating member out of the catheter a first time such that the sharpened distal tip of the tissue penetrating member penetrates at least partially through the wall of the anatomical structure and the outlet opening of the needle becomes situated adjacent said

first location;

D. passing the first engagement member of said attachment apparatus out of the outlet opening of the tissue penetrating member such that said first engagement member will engage the wall of the luminal anatomical structure at said first location;

5 E. retracting the tissue penetrating member into the catheter;

F. repositioning the catheter within the lumen of the anatomical structure;

G. advancing the tissue penetrating member from the catheter a second time, such that the sharpened distal tip of the tissue penetrating member penetrates at least partially through the anatomical structure and the outlet opening becomes situated adjacent said second location;

10 H. passing the second engagement member of said attachment apparatus out of the outlet opening of the needle such that the second engagement member will engage the wall of the anatomical structure at said second location, and the link portion of said attachment apparatus extends between said first location and said second location.

56. The method of Claim 53 wherein steps E-H are repeated at least one additional time to place at least a third engagement member at least a third location on the wall of the anatomical structure.

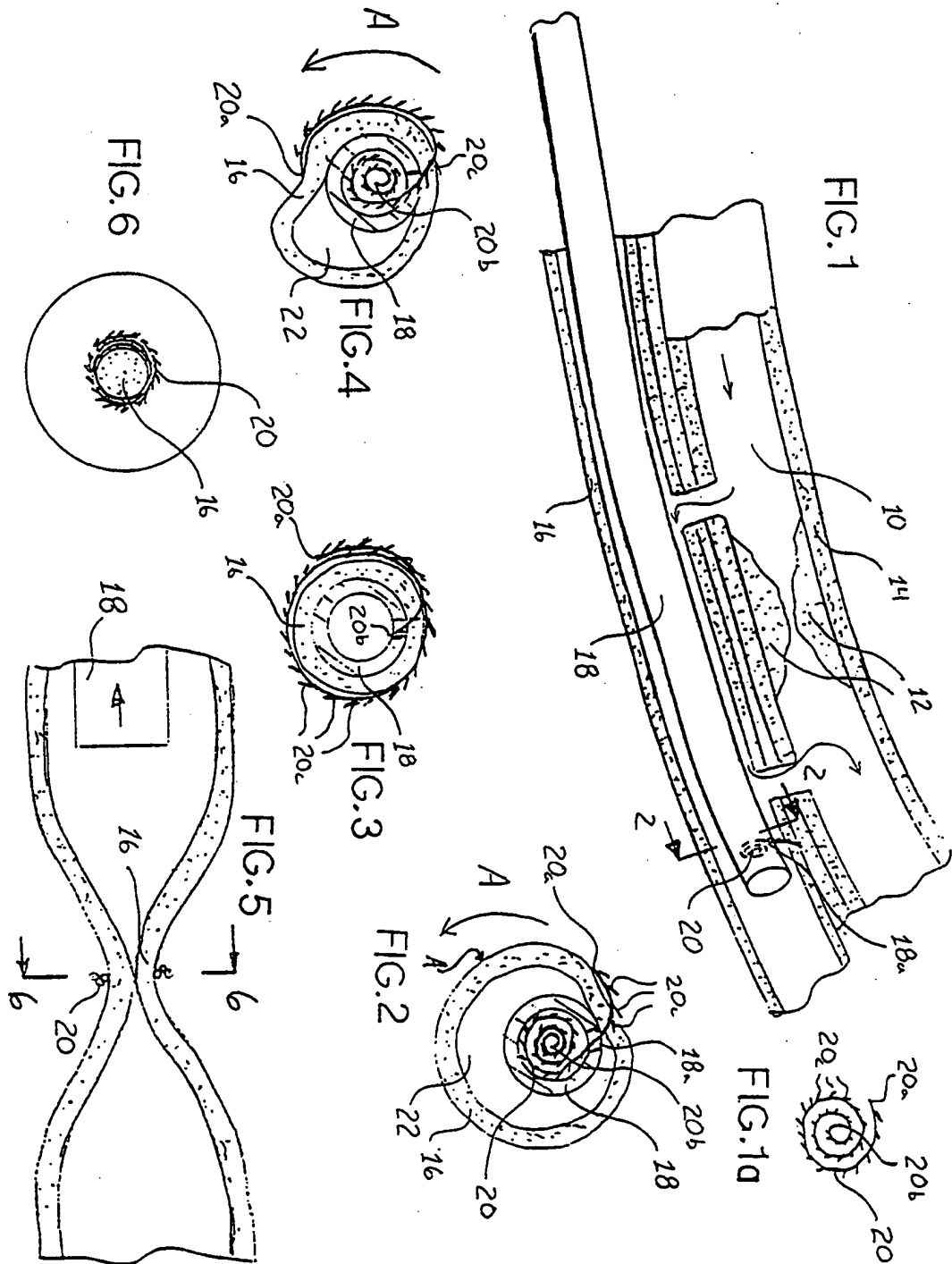
57. The method of Claim 55 wherein the method is performed to attach an article to the wall of the anatomical structure, and wherein the method further comprises the step of:

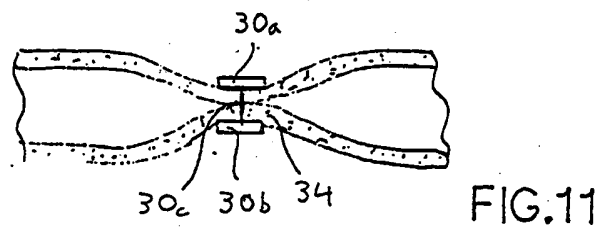
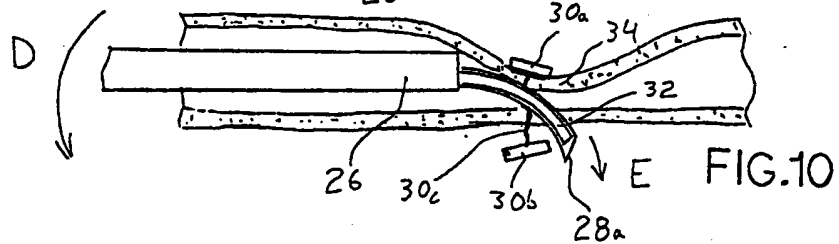
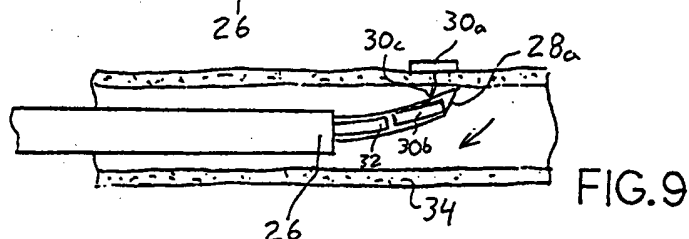
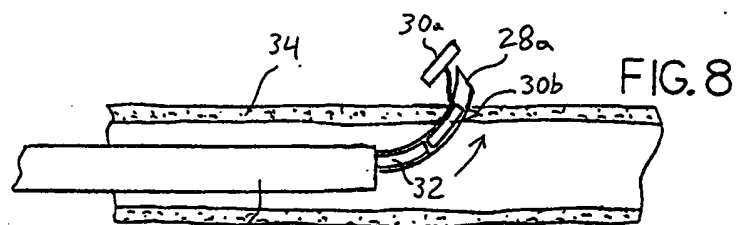
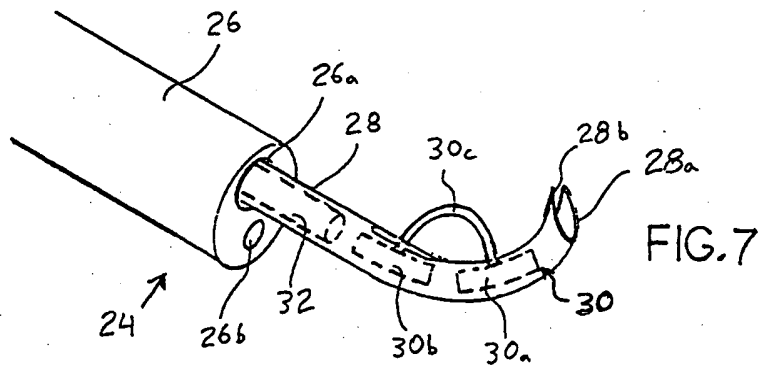
20 positioning the article at a desired location adjacent the wall of the anatomical structure, and wherein the catheter-positioning of step B is performed such that the tissue-penetrating member will pass through a portion of the article as well as through the tissue of the anatomical structure wall.

58. The method of Claim 55 wherein said method is performed for the purpose of forming an anastomotic junction between two segments of said anatomical structure, and wherein said method further comprises the step of:

25 approximating the two segments of said anatomical structure and causing the first and second locations to be positioned such that the attachment apparatus will form an anastomosis between the approximated segments of said anatomical structure.

30





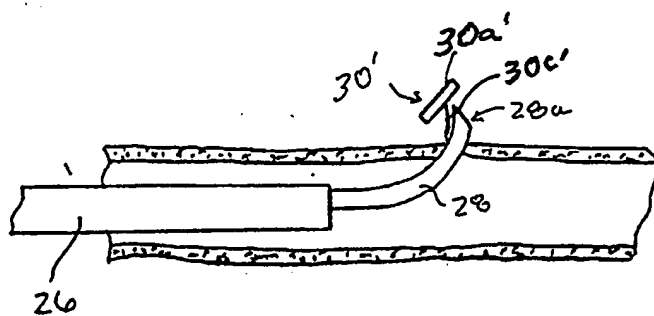


FIG. 12

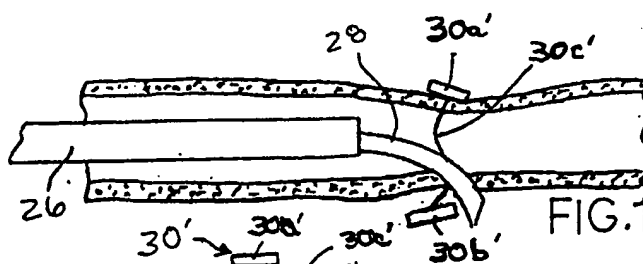


FIG. 13

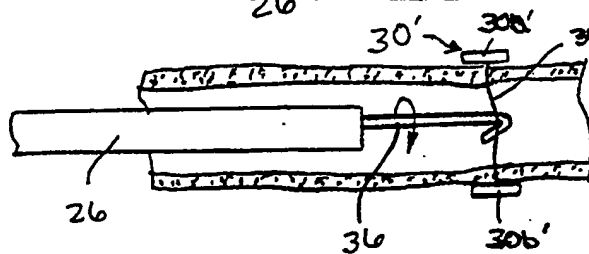


FIG. 14

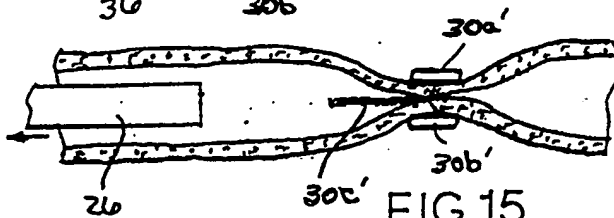


FIG. 15

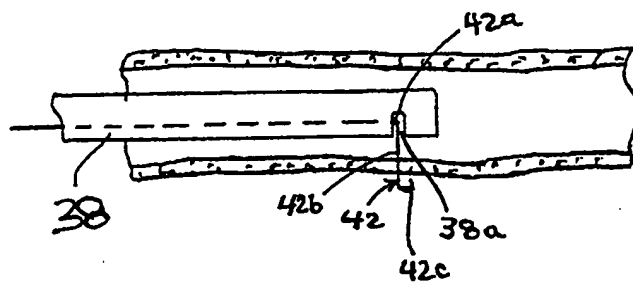


FIG. 16

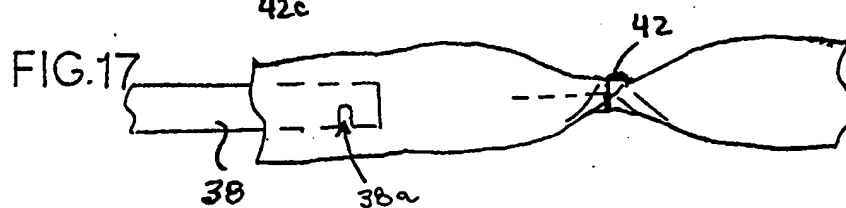
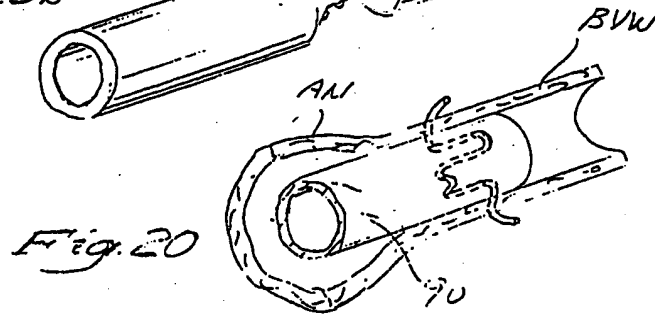
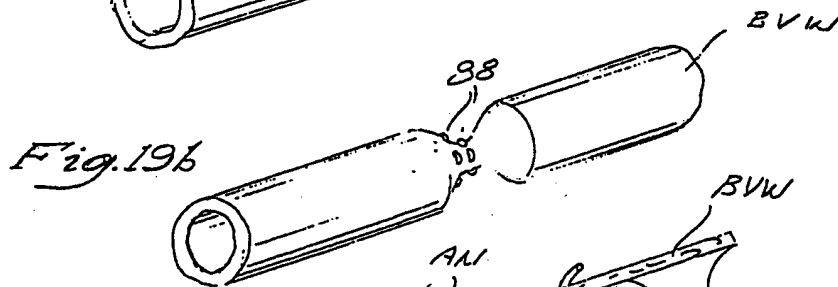
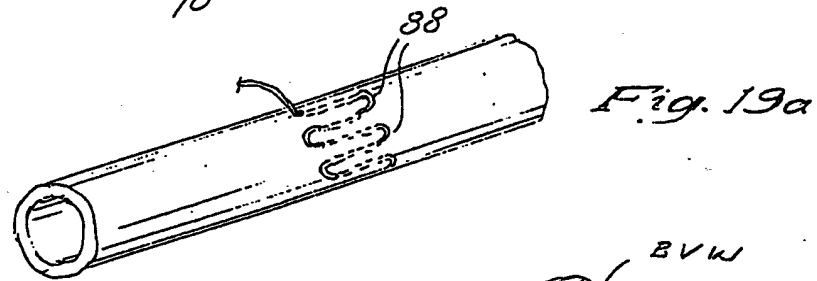
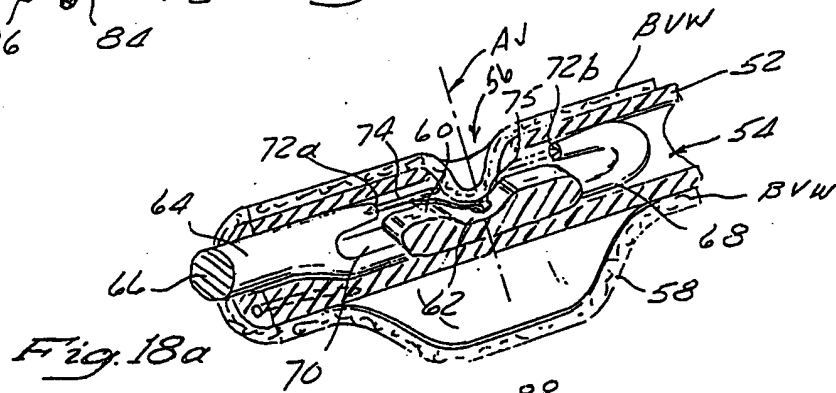
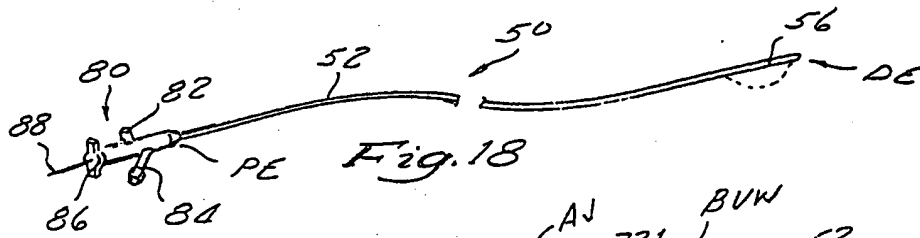
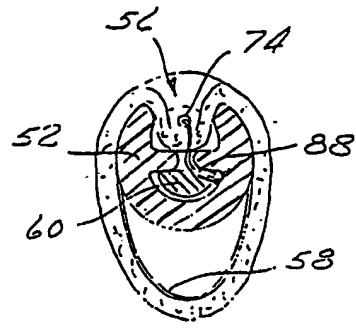
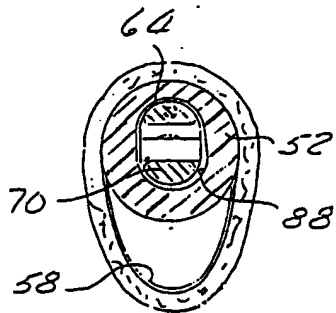
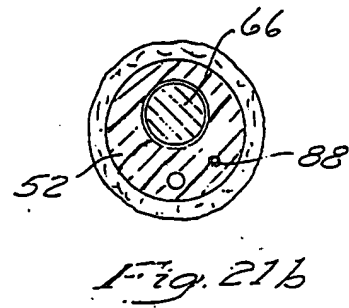
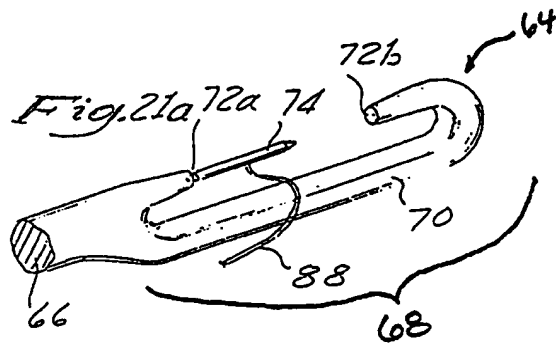
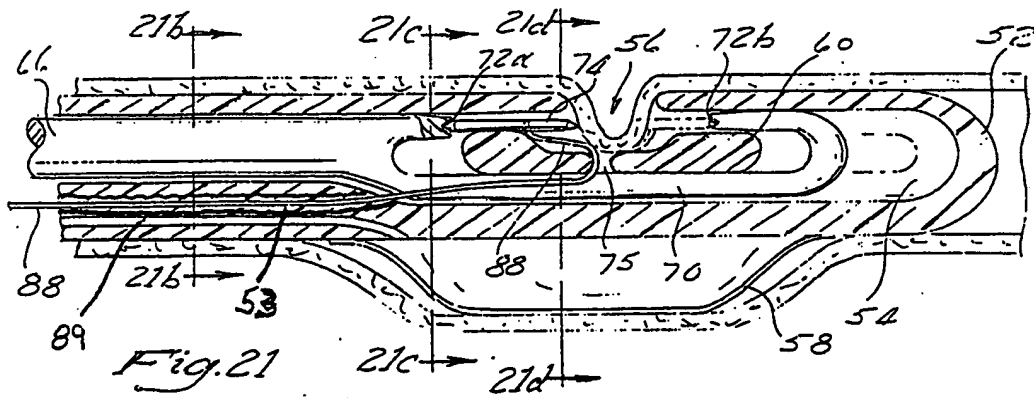
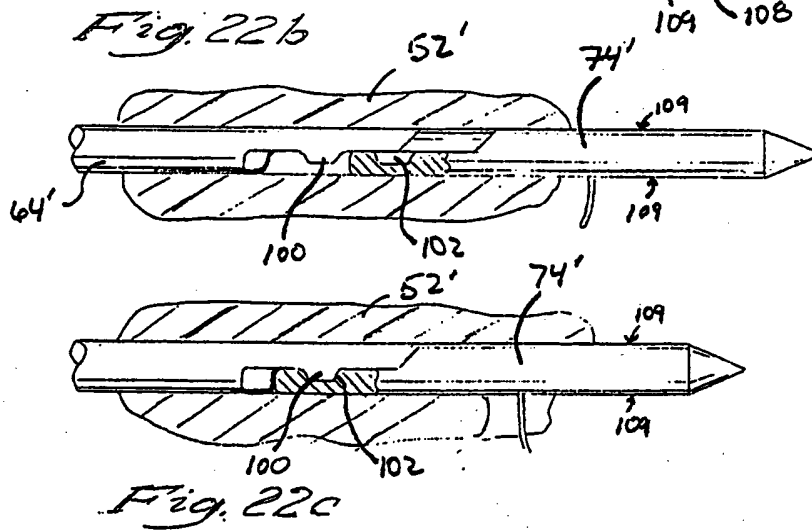
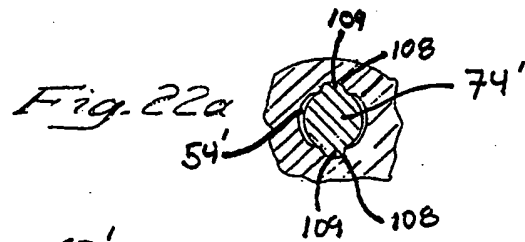
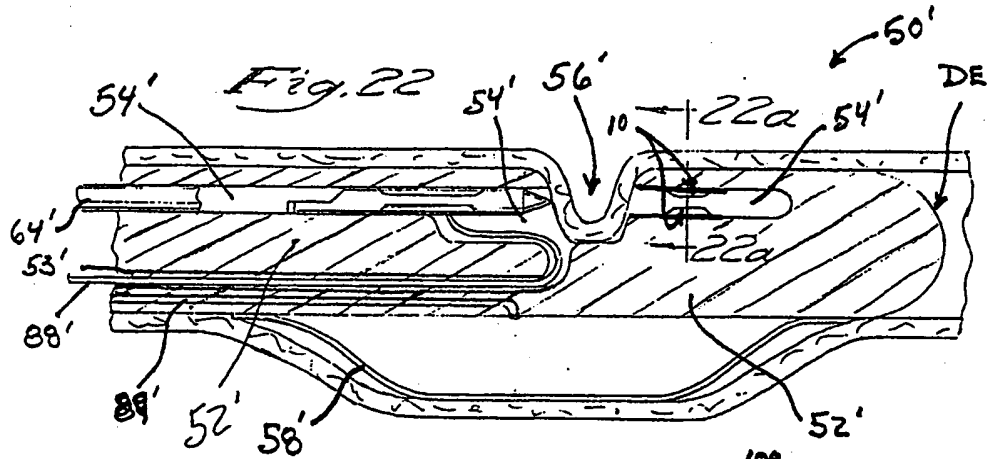


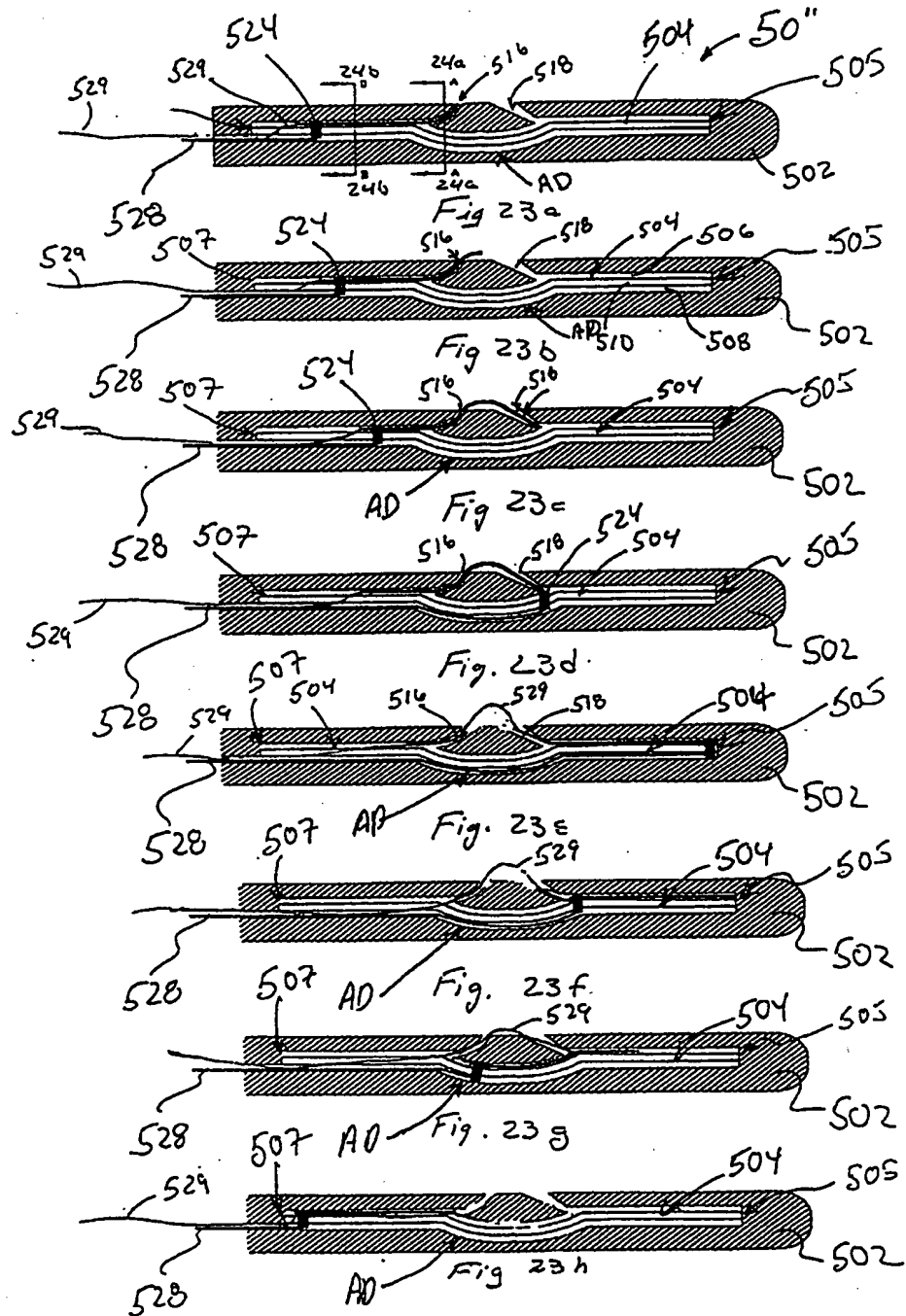
FIG. 17







7/13



8/13

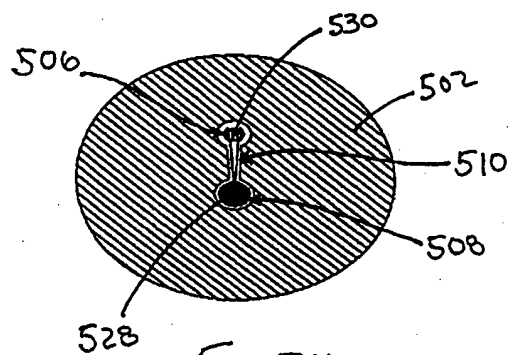


Fig. 24a

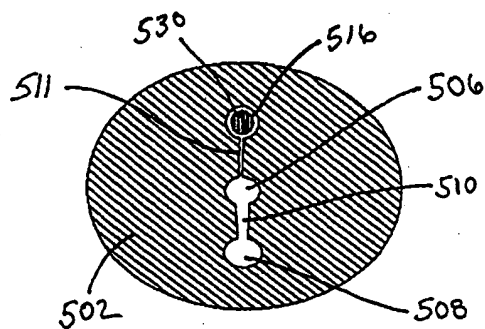


Fig. 24b

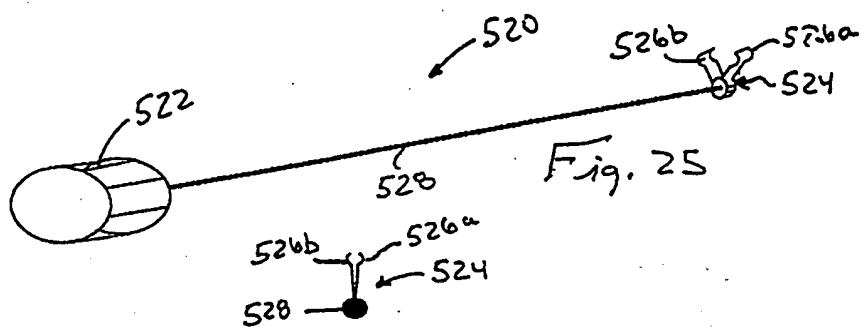


Fig. 25

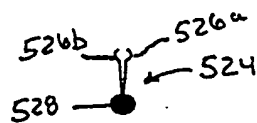


Fig. 25a

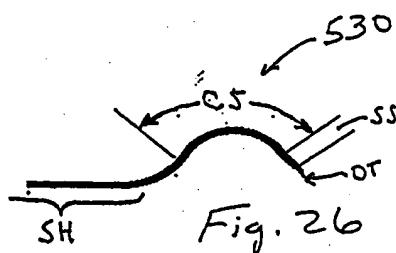
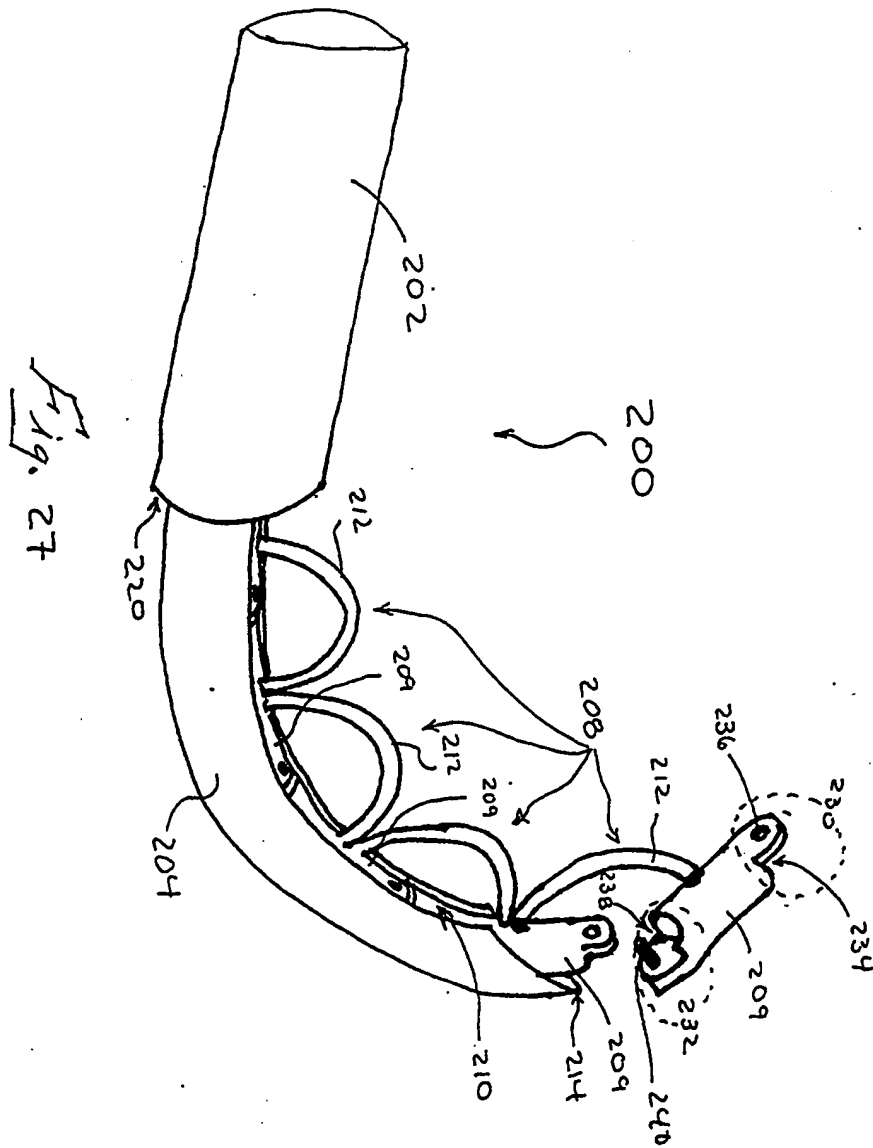


Fig. 26



10/13

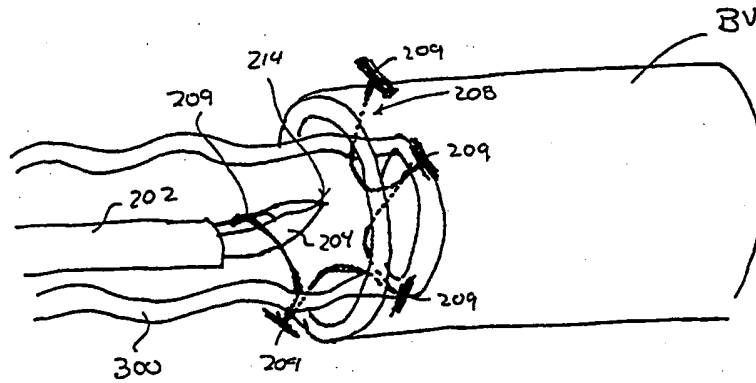


Fig. 27a

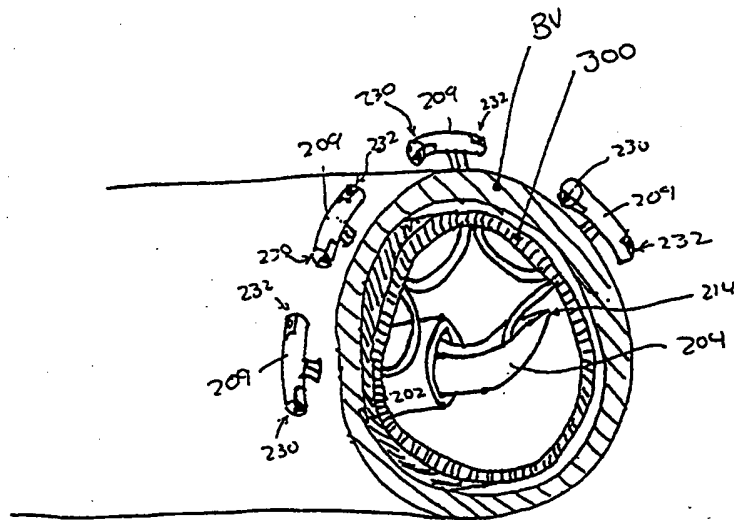


Fig. 27b

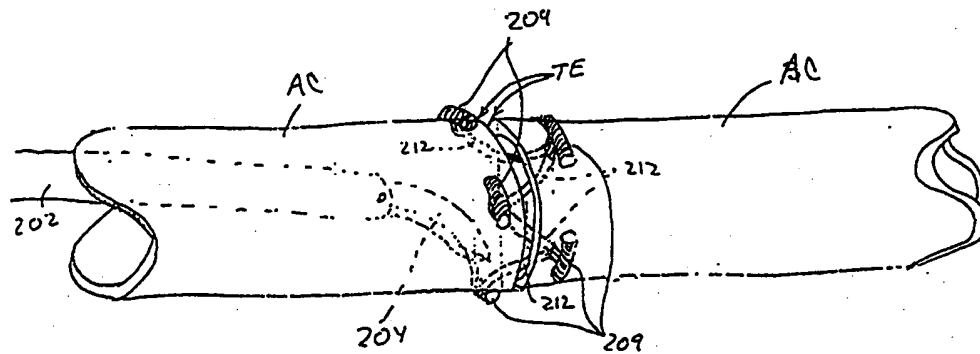
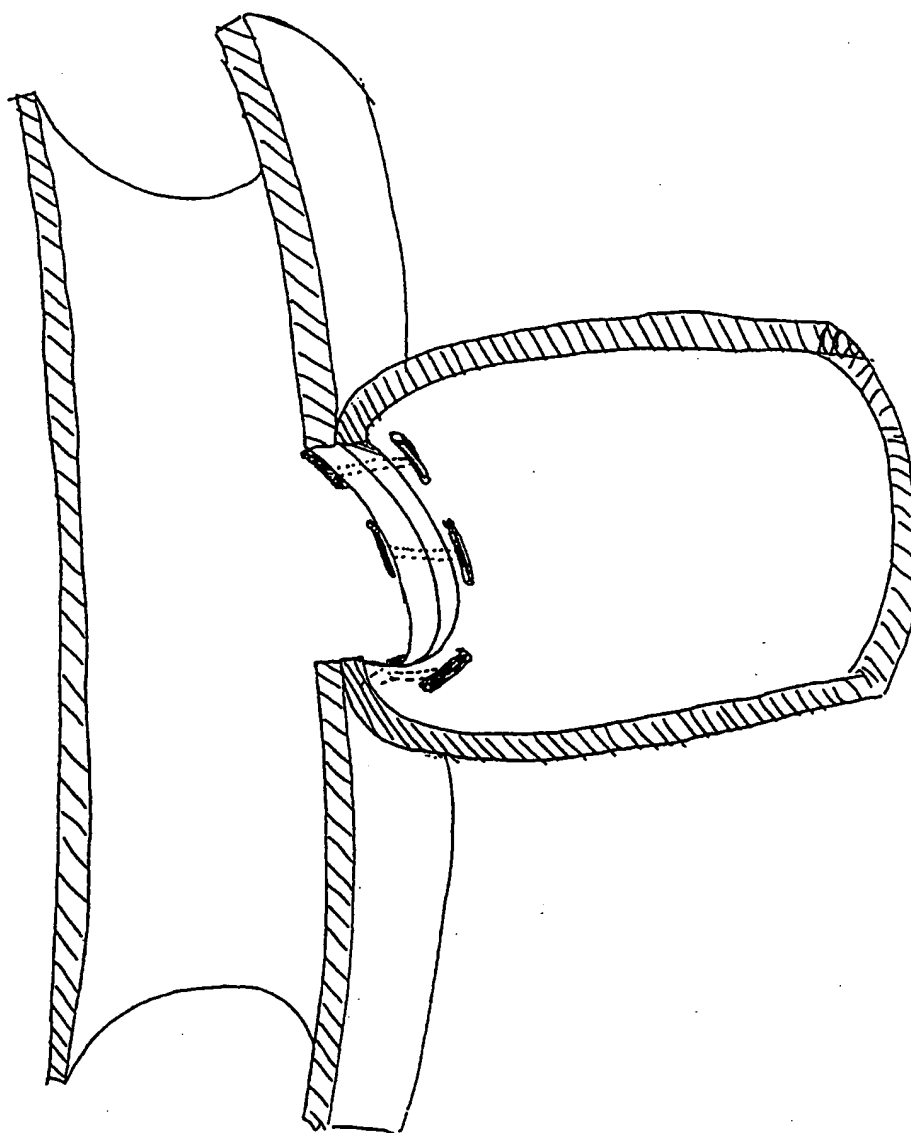
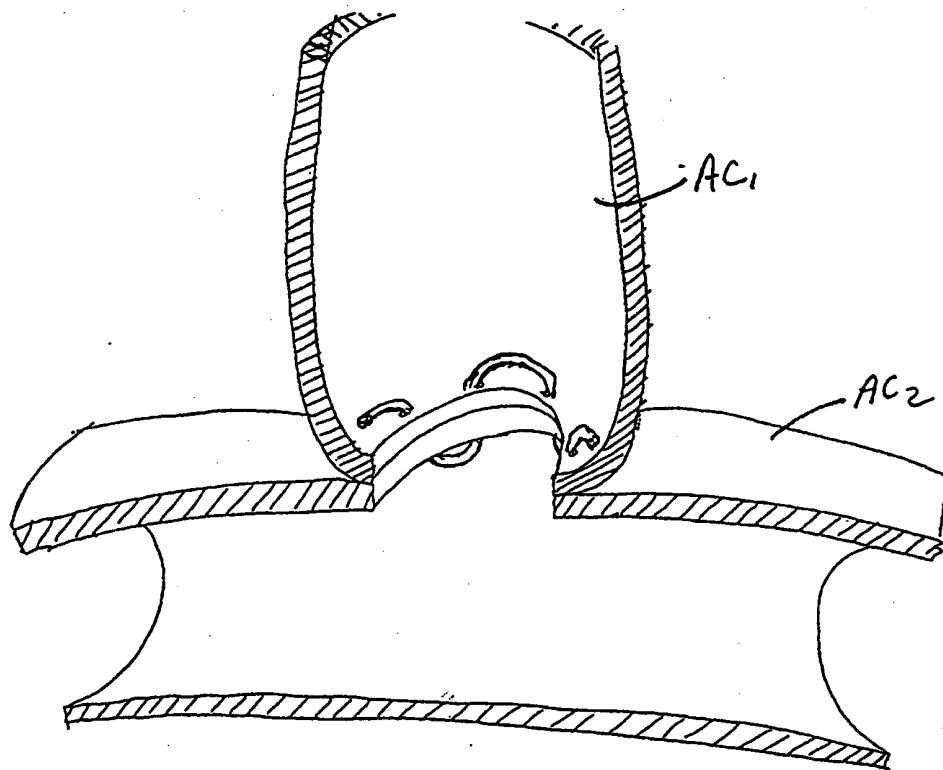
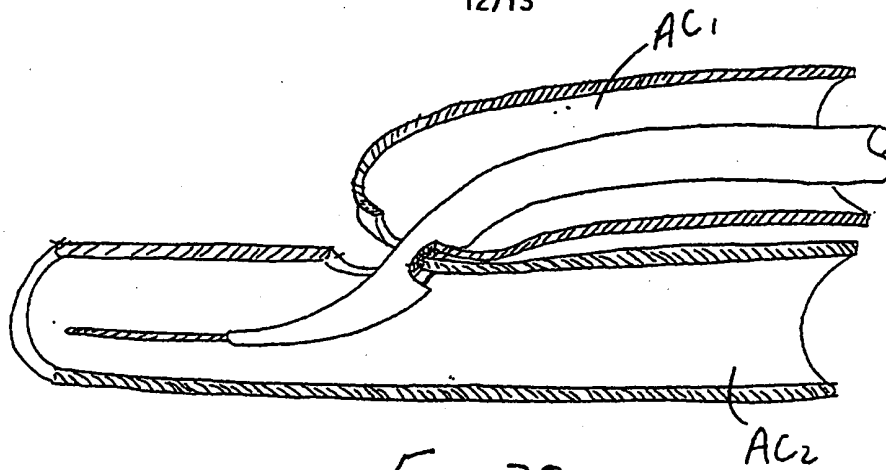


Fig. 27c

Fig. 27d



12/13



13/13

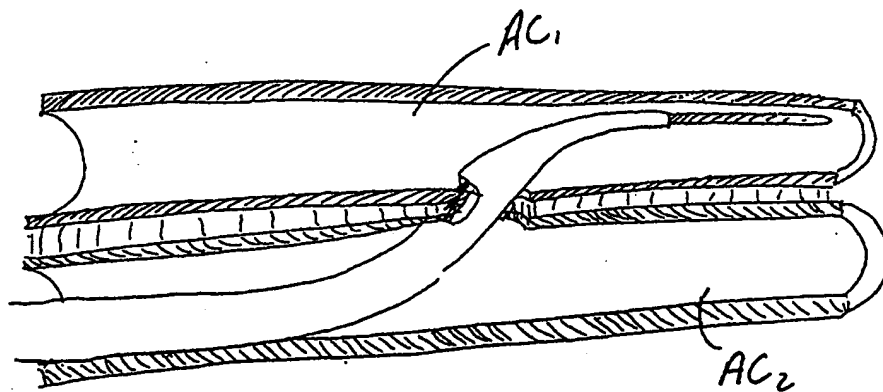


Fig. 29a

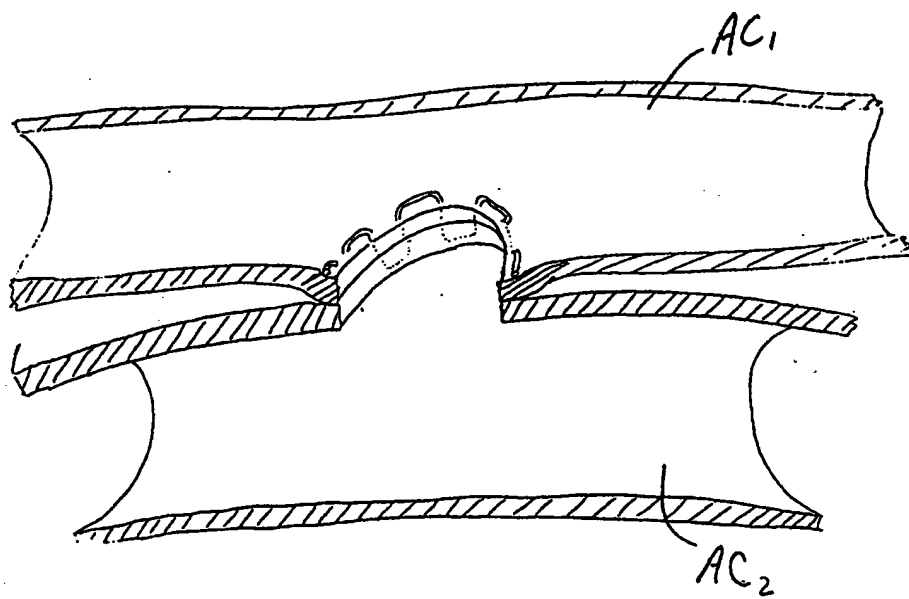


Fig. 29b

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Transvascular, Inc.)
)
International)
Application No: PCT/US98/13342)
)
International)
Filing Date: 25 June 1998)
)
For: Transluminal Methods and)
Apparatus for Closing, Forming)
Attachments to, and/or Forming)
Anastomotic Junctions in, Luminal)
Anatomical Structures)

Authorized Officer: Claus Mantes

RO/US

Assistant Commissioner for Patents
Box PCT
Washington, D.C. 20231

INFORMATION REGARDING PRIORITY CLAIM UNDER PCT RULE 26b1s

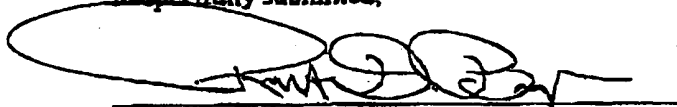
Dear Sir:

Applicant claims priority to United States Patent Application Serial No. 08/896,307 as filed on 28 June 1997. This filing date is correctly shown on the certified copy of the priority document that was transmitted to the International Bureau and is reflected in the Form PCT/IB/304 that was issued on 05 August 1998, a copy of which is appended hereto.

Date: 15 March 1999

4 Venture, Suite 310
Irvine, California 92618
Telephone: 949/450-1750 x213
Facsimile: 949/450-1764

Respectfully submitted,



Robert D. Buyan, Reg. No. 32,460
STOUT, UXA, BUYAN & MULLINS, LLP

PATENT COOPERATION TREATY

PCT

NOTIFICATION CONCERNING
SUBMISSION OR TRANSMITTAL
OF PRIORITY DOCUMENT

(PCT Administrative Instructions, Section 411)

From the INTERNATIONAL BUREAU

To:

BUYAN, Robert, D.
Sereboff & Buyan, LLP
Suite 770
2600 Michelson Drive
Irvine, CA 92612
ETATS-UNIS D'AMERIQUE

Date of mailing (day/month/year) 05 August 1998 (05.08.98)	
Applicant's or agent's file reference TRNSV-017PC	IMPORTANT NOTIFICATION
International application No. PCT/US98/13342	International filing date (day/month/year) 25 June 1998 (25.06.98)
International publication date (day/month/year) Not yet published	Priority date (day/month/year) 28 June 1997 (28.06.97)
Applicant TRANSVASCULAR, INC. et al	

1. The applicant is hereby notified of the date of receipt (except where the letters "NR" appear in the right-hand column) by the International Bureau of the priority document(s) relating to the earlier application(s) indicated below. Unless otherwise indicated by an asterisk appearing next to a date of receipt, or by the letters "NR", in the right-hand column, the priority document concerned was submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b).
2. This updates and replaces any previously issued notification concerning submission or transmittal of priority documents.
3. An asterisk(*) appearing next to a date of receipt, in the right-hand column, denotes a priority document submitted or transmitted to the International Bureau but not in compliance with Rule 17.1(a) or (b). In such a case, the attention of the applicant is directed to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.
4. The letters "NR" appearing in the right-hand column denote a priority document which was not received by the International Bureau or which the applicant did not request the receiving Office to prepare and transmit to the International Bureau, as provided by Rule 17.1(a) or (b), respectively. In such a case, the attention of the applicant is directed to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

<u>Priority date</u>	<u>Priority application No.</u>	<u>Country or regional Office or PCT receiving Office</u>	<u>Date of receipt of priority document</u>
28 June 1997 (28.06.97)	08/896,307	US	24 July 1998 (24.07.98)

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. (41-22) 740.14.35	Authorized officer Diana Nissen Telephone No. (41-22) 338.83.38
--	---

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/13342

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61B 17/08

US CL : 606/157

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/139, 141, 148, 151, 157, 158, 213, 215

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,810,851 A (YOON) 22 September 1998 (22.09.98), entire document.	1, 5-10
X	US 4,621,639 A (TRANSUE et al.) 11 November 1986 (11.11.96), entire document.	1-4, 12-19, 22, 41-48
X	US 5,431,666 A (SAUER et al.) 11 July 1995 (11.07.95), entire document.	23-27
X	US 5,527,322 A (KLEIN et al.) 18 June 1996 (18.06.96), entire document.	23, 27, 32, 33, 36-39, 49-54, 56

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
B earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*Z* document member of the same patent family
O document referring to an oral disclosure, use, exhibition or other means	
P document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

25 SEPTEMBER 1998

Date of mailing of the international search report

23 OCT 1998

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

TINA T. D. PHAM

Telephone No. (703) 308-0824

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☐ FADED TEXT OR DRAWING
- ☒ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☐ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.

THIS PAGE BLANK (USPTO)